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FAMILY PLANNING PROGRAMS

Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

# Breast-Feeding, Fertility, and Family Planning

**Editors' Summary**. Breast-feeding is the best form of nutrition for the young infant and an important means of spacing births. In most developing countries almost all women breast-feed their children initially, but there is evidence that the length of breast-feeding is declining, especially in urban areas. Family planning workers should encourage women to start and to continue breast-feeding because it is important for infant health and contributes to child-spacing. It is unreliable as a method of family planning for individual women, however. After 6 to 12 months or as soon as the infant begins to receive a substantial amount of other food regularly and suckles at the breast less often, fecundity is likely to return, and effective contraception is needed to avoid another pregnancy.

Breast milk has special properties that make it superior to even the most carefully made home or commercial preparations. It not only provides immunological protection against common childhood illnesses such as diarrhea and respiratory disease but also helps to maintain a protective environment within the intestine. It contains the complete range of nutrients necessary to the young infant and is easier to digest than substitutes.

In developing countries, infants may face special hazards when breast-feeding is curtailed. The high cost of proper bottle-feeding—$200 to $300 (US) in the first year—may lead parents to dilute commercial or home preparations. Water supplies are often polluted, and facilities for sterilization and refrigeration are scarce. As a result, bottle-fed babies are more likely than breast-fed babies to be malnourished, to be sick, and in some cases to have higher death rates. Although upper income families usually can compensate for some of the disadvantages of bottle-feeding, poor families who start to bottle-feed without realizing all the problems that are involved may be endangering a child's health.

### Breast-Feeding Declines

Recent evidence suggests that the length of breast-feeding in many developing countries is declining. For example, in Taiwan and Thailand over the last decade the average length of breast-feeding has dropped by about five months. Better educated, more affluent, urban women are likely to breast-feed for shorter periods if at all. By contrast, in the US, Sweden, and Australia, breast-feeding is becoming more prevalent, especially among educated women, although the average length of breast-feeding remains short.

At any one time 10 to 40 percent of married women of reproductive age in developing countries may be breast-feeding. The percentage of women who breast-feed *initially* is high throughout the developing world—about 90 percent in 28 countries surveyed. But there is some variation—for example, between Bangladesh, where 98 percent of women start breast-feeding, and Costa Rica and Malaysia, where 74 percent start. There is even more variation in the *length* of breast-feeding—from 30 months in Bangladesh to 2 in Costa Rica.

Why are women in developing countries breast-feeding less? The reason most commonly given in surveys is "insufficient milk." Yet well-nourished women in cities and developed areas are more likely to give up breast-feeding than malnourished rural women who may produce less milk. Women who say that they do not have enough milk may actually not know how to breast-feed properly, or may not have the help and support they need from family or friends, or may prefer not to breast-feed for other reasons. Some advocates of breast-feeding blame widespread advertising and promotion of infant formula for the decline of breast-feeding. Others cite practices of hospitals and health personnel which separate the mother and newborn infant and sometimes discourage breast-feeding. Still other observers note that more women now work in nonagricultural jobs where it is difficult to breast-feed.

Physiologically, the amount of milk a woman produces depends much more on the frequency, duration, and intensity of infant suckling than on maternal nutrition, age, or parity. Thus rural women, even if they are poorly nourished, can often breast-feed for prolonged periods because infants may suckle 12 to 14 times a day. Women who try to adopt a regular 3- to

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Phyllis T. Piotrow, Ph.D., Director; Walter W. Stender, Associate Director; Ward Rinehart, Editor

4-hour schedule, however, may find that their milk supply diminishes as nursing frequency is reduced and other infant foods are introduced.

### Contraception and Breast-Feeding

In general, the longer a woman continues to breast-feed, the longer she will be protected against pregnancy. Full breast-feeding, with frequent suckling, night feeding, and no other food for the infant, delays the return of fertility longest because it allows for the most suckling. As suckling diminishes, so does milk production and the protection against pregnancy. But even in fully breast-feeding women, ovulation may occur and menses resume. By six months about 20 to 50 percent of breast-feeding women are menstruating and need contraception just as much as if they were not breast-feeding.

With respect to contraception and breast-feeding, two different concerns must be addressed: (1) during prolonged breast-feeding, contraception is needed to prevent another pregnancy too soon; and (2) where the duration of breast-feeding is declining, greater contraceptive use is needed to prevent fertility from increasing.

Most contraceptive methods—IUDs, voluntary sterilization, barrier methods, withdrawal, and abstinence—have no effect on lactation. They can be used as safely by breast-feeding women as by other women. With respect to hormonal contraceptives, some questions have been raised and not yet resolved. A number of studies suggest that combined estrogen-progestin oral contraceptives may reduce the amount of breast milk or the length of lactation in some women. Infant growth has not been affected, however, by pills containing 0.05 mg or less of estrogen. Still, some authorities advise against using any combined oral contraceptive—at least until lactation is well-established. Progestin-only contraceptives either have no impact or, in the case of some compounds, such as depot medroxyprogesterone acetate (DMPA), appear to increase the volume of breast milk produced. With all hormonal contraceptives, a small amount of hormone reaches the breast-fed infant. Although long-term research has not been conducted, there have been no reports of serious adverse effects to date.

### Implications for Family Planning Programs

Before definitive guidelines on breast-feeding and contraception can be established, a better understanding of breast-feeding and lactational infecundity is needed, along with detailed knowledge of local conditions and individual experience. Still, these suggestions are offered as reasonable options, based on current knowledge and program experience:

- All women should be encouraged to breast-feed their children initially and for as long as feasible.
- Extra food for the mother should begin at the start of pregnancy and continue throughout lactation to help maintain the mother's nutritional status and perhaps also to improve her breast-feeding performance.
- Breast milk alone is usually sufficient for the infant until four to six months of age if the mother is adequately nourished. After four to six months an infant should receive supplemental feedings.
- A fully breast-feeding woman usually does not need contraception before six months postpartum. Sometimes, however, IUD insertion or voluntary sterilization can be performed just after delivery. Supplies and instructions for other methods can be provided then or at a postpartum checkup.
- To minimize any adverse impact on milk volume or length of lactation, or any drug transfer, progestin-only pills may be the best hormonal method, followed by injectables or the lowest available dose of combined pills (0.05 mg or less estrogen). The US Agency for International Development (USAID) plans a limited purchase of progestin-only pills in 1982. Where progestin only methods are not available, the advantages of low-dose combined pills in preventing another pregnancy—with its reduction in milk supply and strain on maternal health—may outweigh any potential disadvantages.
- No universal rule is possible to determine when a breast-feeding woman can start hormonal methods. A woman who allows frequent suckling day and night with little supplementation and is not menstruating might reasonably wait 12 or 18 months to start combined pills or might start progestin-only methods earlier. A woman on a 3- to 4-hour, day-only feeding schedule who gives the infant other food early might reasonably start two or three months after delivery.
- Waiting for first menses involves some risk of pregnancy, but after first menses effective contraception is essential. Supplies and instructions should be ready in advance.
- To maintain adequate milk supply, frequent suckling should be encouraged. When mothers start hormonal contraceptives, they should be cautioned about changes in their activities that might interfere with the frequency and duration of suckling.
- Family planning programs should provide a range of methods, including hormonal and nonhormonal methods, for breast-feeding women. Programs that either do not offer nonhormonal methods or discourage use of hormonal methods during lactation may increase the risk that women will stop breast-feeding in order to use the method which is available or preferred or, alternatively, that they will become pregnant while breast-feeding.

An unwanted pregnancy during breast-feeding is a proven and serious risk to the health of the mother and eventually to the health of both children. Avoiding such pregnancies should have high priority for family planning and maternal and child health personnel. **End of Editors' Summary.**

## BENEFITS OF BREAST-FEEDING

Breast milk is the best food for infants, and no substitute food exactly duplicates it. Studies of breast milk and breast-feeding show that:

- Breast milk provides some immunological protection for the infant.
- Breast milk best satisfies the infant's nutritional needs.
- Breast-feeding costs less than feeding with substitutes.
- Because of the immunological and nutritional advantages of breast milk and because preparing substitutes properly is difficult in much of the developing world, breast-fed infants are less likely to develop infections or malnutrition.
- Breast-feeding protects against pregnancy, although the length of this contraceptive effect is not predictable.

Many other advantages have been claimed for breast-feeding, ranging from closer emotional ties between mother and child to greater intellectual ability in later life for the breast-fed child. Such possible benefits are difficult to measure, and more research will be necessary before any or all can be accepted.

### Immunological Protection

A major advantage of breast-feeding is immunological protection. Unlike other infant foods, both colostrum and mature breast milk contain biologically active substances that guard the infant against infection (89, 214, 274, 330, 366, 439, 470, 595, 604). The concentration of these substances is highest in the colostrum, the high protein fluid secreted in the first days postpartum, when the infant's immune system is still immature.

There are a number of immunologically protective agents in human milk, including:

- immunoglobins, which produce antibodies against specific bacteria and viruses (173, 215, 366, 595),
- leukocytes, which destroy bacteria and other foreign substances (173, 386, 396),
- the bifidus factor, which promotes the growth of bifid bacteria, the predominant intesinal flora in breast-fed infants, which in turn prevent the growth of potentially harmful organisms (67, 330, 366, 595).

As a result, breast-fed infants are less likely to develop gastrointestinal disease (109, 144, 495, 610) and viral respiratory infections (109). Breast-fed babies are also less likely to contract middle ear infections (108, 109, 230, 495), either through immunological protection or because holding the infant prone during bottle-feeding allows regurgitated milk to pool in the eustachian tubes, creating a medium for bacterial and viral growth (41, 177, 595). In addition, a number of allergies, including eczema, cow's milk allergy, and allergic rhinitis, are less common among breast-fed infants (367, 397).

### Nutrition

An adequate supply of human breast milk satisfies virtually all nutritional needs of an infant for the first four to six months of life (22, 128, 153, 261, 274, 610, 614). After supplementary foods are introduced, breast milk can remain an important source of protein and other nutrients for many months (23, 47, 610, 616).

**Breast-feeding provides the best protection against infection and the most nutritious food for the young infant. Breast-feeding also accounts for a substantial amount of child spacing in some countries, but it is not a reliable method of family planning for individual women.** (FAO)

# NUTRITIONAL NEEDS OF BREAST-FEEDING WOMEN

How much does a woman's diet affect her ability to breast-feed and her child's growth? Can dietary supplements help poorly nourished mothers produce more milk? Surprisingly, research to date has not resolved these questions.

Evaluating the volume and composition of breast milk is exceedingly difficult. No one knows the optimal yield of breast milk for any individual woman (634). The amount produced varies widely, from over 1,000 ml to less than 400 ml, and appears to depend on many different factors, such as birthweight, age, and activity level of the infant, season of the year (277, 431, 583), suckling patterns (255, 569), and even the process of measurement itself (106, 277, 633, 673).

A number of studies worldwide suggest that poor nutritional status diminishes both the volume and probably also the fat and vitamin content of breast milk, although nutritional studies often cannot either record or control adequately all of the factors involved (9, 27, 167, 205, 213, 277, 580, 581, 614, 634, 645, 665, 666). In the Gambia, for example, women who usually produced about 66 grams of milk per feed produced only about 42 grams per feed during the rainy season, a traditional "hungry time" when caloric intake is low and energy expenditure is high because of intense farming activities (431, 583). Also, during the rainy season levels of fat and B-vitamins in breast milk were lower (665). Similar seasonal variations are reported in Zaire and Kenya (227, 678). In Mexico a group of poorly nourished women produced low quantities of milk ranging from less than 400 ml to 650 ml per day (91). What this means for the infant, as Joe D. Wray has pointed out, is that

> a mother producing 500 cc/day of 65-calorie milk, rather than the 800 cc of 75-calorie milk that a well nourished woman can produce, will, in effect, produce 50 percent fewer calories and equivalent deficits of other nutrients. (614)

Nevertheless, it is evident that, except at extremes of starvation or malnutrition, poorly nourished women are able to breast-feed their children and often do so for longer periods of time than women who are better nourished. As Derrick and E. F. Patrice Jelliffe have pointed out,

> The volume and composition of human milk in poorly nourished women is surprisingly good, possibly due to some metabolic adaptations, but probably usually to their cumulative nutritional detriment ("maternal depletion") (277).

An Indian study compared lactating and nonlactating groups, both of which had diets of 1,200-1,600 kcal per day. The lactating women showed a decrease in body weight, arm circumference, and skinfold thickness, indicating that body fat was being utilized to produce milk. Nevertheless, after 12 months, the lactating women weighed only 2 kg less than the nonlactating women (456). This suggests that some process of metabolic adaptation, possibly due to higher prolactin levels, occurs in lactating women, allowing energy balance to be maintained on what would appear to be an inadequate diet (347, 456).

Even so, lactation can impair a poorly nourished woman's health. When nutrition is poor, the mammary glands draw upon maternal body fat and other reserves to produce milk (167, 431). Repeated pregnancies and lactation, often combined with continued hard physical labor, lead to general protein-calorie malnutrition, weight loss, prematurely aged appearance, and various nutritional diseases (455, 632, 651).

Both lactating and pregnant women require more calories, protein, and other nutrients than other women. Nutritional requirements are greater for lactating women than pregnant women because normal infant growth is more rapid than fetal growth, and fewer of the infant's body functions, such as maintenance of body heat, are performed by the mother's body (591). It is not clear, however, if supplementing a lactating woman's diet will increase her milk supply.

Only a few studies have examined the effect of maternal supplementation, and the results are mixed. Milk volume increased with supplementation in four studies (91, 143, 176, 518), but in three other studies there was no change in either milk production or infant weight (114, 176, 460). Methodological problems in many of these studies make interpretation difficult, however. In a Nigerian study, for example, infants' daily weight gain rose significantly—from 30.4 to 45.7 grams—when their mothers received a skimmed milk supplement that doubled the protein content of their diets. The mean volume of milk also rose significantly, although the concentrations of protein, lactose, and milk solids did not change (143). The mothers were hospitalized during the course of the study, however. This reduction in their workload could have allowed additional calories to be used for milk production.

Maternal supplementation programs may show no increase in milk production for several reasons:

- The woman may give the supplement to her children or husband or substitute it for other foods she eats (646).
- The supplement may be insufficient to make up the entire caloric deficit (460).
- Supplementation only after delivery and not during pregnancy may be inadequate (91).

Attention is now focusing on the total energy needs of pregnant and lactating women and the metabolic processes by which poorly nourished women are able to breast-feed for long periods without apparently adequate supplementation. Ideally, lactation depends on fat reserves, about 3.5 to 4 kg accumulated before and during pregnancy (281, 402), as well as on diet during lactation. Undernourished women may gain only 5–7 kg altogether during pregnancy and thus be unable to develop the necessary "fat bank" for adequate milk production (649). For these women, food supplementation might have to begin at least by the last trimester of pregnancy in order to improve breast milk production.

The process of reproduction, including both pregnancy and lactation, places a heavy burden on poorly nourished women that is still not fully measured or understood. Increased recognition of the value of breast-feeding for infant health should therefore be accompanied by increased emphasis on better nutrition and above all on more effective child-spacing for the mother.

Among different mammals, maternal milk appears to be adapted to the offspring's particular needs. The composition of milk varies considerably among mammalian species (208, 389, 640). Furthermore, the composition and quantity of human milk varies among mothers and for each mother from the beginning to the end of each feeding, from feeding to feeding, and over the months of breast-feeding (13, 53, 156, 207, 221, 253, 486, 583, 603, 610). It has been hypothesized that some of these differences correspond to the individual infant's needs (274). There is some evidence that the milk composition in mothers of premature infants differs from that in mothers of full-term infants. This suggests that it may be especially suited to premature infants (4, 28, 29, 44, 194, 497).

No substitute is the nutritional equivalent of human breast milk. Cow's milk, which is the most common replacement for breast milk in Western cultures (274), has a lower proportion of fat and lactose and a higher proportion of protein than human milk (152, 208). It is more difficult to digest than breast milk and more likely to produce constipation (41, 172, 330, 595).

The commercially prepared infant formulas, which are mostly derived from cow's milk, have not yet duplicated the average composition of human breast milk (208, 330, 595). Further, no substitutes can match the differences between feedings and over time.

### The Economics of Breast-Feeding

Breast-feeding is usually less expensive than bottle-feeding, but, in calculating relative costs, several comparisons must be considered:

- the direct monetary costs of the breast milk substitute and its preparation compared with the cost of the mother's added nutritional intake, if any,
- the value of time spent on breast-feeding compared with time spent on alternative feeding methods,
- the indirect costs of bottle-feeding—increased infant morbidity and mortality—compared with the indirect costs of breast-feeding—maternal depletion among malnourished women.

In the aggregate, the infant feeding choices made by individual families can have an economic impact on a nation.

Bottle-feeding requires the purchase not only of the breast milk substitute, but also of the bottle and nipple. It requires fuel for sterilization of the equipment and, ideally, refrigeration (47, 190, 274, 330, 372). These costs vary, but generally the cost of proper feeding with a breast milk substitute totals at least $200–$300 (US) for the first year of life (47, 78, 190, 330, 372, 471, 605). Among substitutes, commercial infant formula is generally more expensive than modifying and preparing milk products in the home (47, 190, 372, 446).

Poor families may spend less than $200–$300 a year on bottle-feeding, but the child may suffer as a result. To save money, families may not give enough formula or may overdilute it (526). They may use milk from cows or other animals without modifying it. They may even mix flour and sugar with water so that it simply looks like milk (120). A full estimate of the expense of bottle-feeding should include the cost to the family and to society of resulting increases in infant morbidity and mortality when bottle-feeding is inadequate or improper (47, 190).

The only direct monetary cost of proper breast-feeding is dietary supplementation of the mother before and after delivery (see box, p. J-528). These extra nutritional needs can sometimes be met by additional quantities of inexpensive foods already in the woman's diet, which cost less than bottle-feeding (113, 190, 330, 372). Many women do not or cannot augment their diets while breast-feeding, however, and therefore a full estimate of breast-feeding costs should also include the costs to the family and society of related maternal health problems and, if milk supply is inadequate, child health problems (212).

Even more difficult to assess are the relative time requirements of breast- and bottle-feeding. Breast-feeding is more time-consuming for the mother (3, 136, 404 442), while bottle-feeding, although it requires much preparation, can be delegated, thus enabling the mother to work outside the home (69, 190, 404, 442). For a woman at the lower end of the wage scale, the cost of infant formula may be about half of her income, resulting in little economic gain (47, 78, 189, 190, 445, 471). For women who can command higher wages, the mother's income, even after subtracting the cost of bottle-feeding, can make a substantial contribution to household income (190, 442). Providing creches, or nurseries, at the work place and allowing nursing breaks during the work day would reduce the personal costs but raise the costs to the employer and to society.

The use of infant formulas may affect national as well as family finances (274, 322). Many breast milk substitutes, particularly commercial infant formulas, are imported and thus must be bought with scarce foreign exchange funds (166, 322). In the past decade the price of importing skim milk powder, for example, has increased sharply—from $300–$400 (US) per ton in 1972 to about $1,500 per ton in 1977 (369). While dried milk is sometimes donated as development assistance, the quantities are small and erratic, since they are related primarily to excess production in the donating country (251).

Menyusui Sendiri
sesuai dengan anjuran agama
وَالْوَالِدٰتُ يُرْضِعْنَ اَوْلَادَهُنَّ حَوْلَيْنِ
كَامِلَيْنِ لِمَنْ اَرَادَ اَنْ يُّتِمَّ الرَّضَاعَةَ
Para Ibu hendaklah menyusukan anak anaknya selama dua tahun penuh, yaitu bagi yang ingin memempurnakan penyusuan. (Al baqarah 233).

**This Indonesian poster repeats the injunction of the Koran: "Mothers shall nurse their children for two whole years. . . ."**

## INFANT FOOD SUPPLEMENTATION

Infant food supplementation, or weaning, is the process by which foods other than breast milk are introduced.

Patterns of food supplementation vary widely in different cultures. Supplementary foods are given to infants as early as one to two months or as late as 18 months (3, 23, 73, 128, 199, 227, 303, 351, 355, 380, 384, 395, 466, 513, 577, 605). In a WHO 9-country study on breast-feeding, for example, more than half of the rural Chilean women were regularly supplementing their infants' diets at age two to three months, compared with only 2 percent of the rural Indian women. Among the urban poor Ethiopian women, 12 percent still had not begun food supplementation as late as 18 months postpartum. Types and amounts of food given also varied widely, depending on the products locally available. When infants are offered supplementary food in the first six months, in Zaire the food is generally cereal and legumes; in India, only milk or milk products (605).

When should supplementation start? It has been widely recommended that infants receive only breast milk for four to six months (22, 128, 153, 261, 610). In developed countries, although physicians once routinely recommended very early introduction of solid foods, this practice is now discouraged since the infant's digestive system is then too immature to absorb complex foods. In addition, supplementary foods expose the infant to risk of infection and, if given in large enough amounts, reduce the infant's inclination to suckle at the breast.

In developing countries, however, when the nutrition of the mother is poor, supplementary food may be needed earlier (91, 486, 610). Surveying 17 studies of infant growth in developing countries, J. C. Waterlow and colleagues note that the rates of growth fell off substantially at three to four months or earlier when compared with growth rates of infants from the United Kingdom (571). Henri Vis notes that in central Africa the growth of rural infants begins to falter at two or three months (679). Whether breast-fed infants in developing countries should be following the same growth curves as bottle-fed infants in developed countries is not clear, however, and a slower pattern of growth may be normal for breast-fed infants (234).

Even when the mother's milk supply is ample, supplementation should start no later than six months. Delaying supplementation beyond six months deprives the child of nutrients. In the WHO study, infant weight gain was unusually slow in infants who did not receive any food until after six months (610).

Techniques of supplementary feeding are important. Infants should always be breast-fed before getting solids or formula since breast milk is the more valuable food. The supplementary foods should be given with a cup and spoon, not a bottle. Cups and spoons are easier to clean than bottles and nipples and thus safer for the infant. Moreover, if bottles are used, infants may find them easier than breast-feeding and reject the mother's breast (41, 604). In general, other foods should not replace breast milk, especially for young infants.

### Impact on Infant Health

Given the immunological and nutritional benefits of breast-feeding as well as the hazards of substitutes used where they are not appropriate, the practical question is: Does feeding with other preparations, whether commercial or homemade, instead of breast-feeding, have a major impact on infant health and development?

Answers vary, depending on circumstances. On one hand, most studies of small groups living under similar conditions in developed and developing countries tend to show that breast-fed infants experience less illness and lower death rates than bottle-fed infants. On the other hand, the fact that infant mortality is lowest in the developed countries and among the upper socioeconomic groups in developing countries, where bottle-feeding has been most common, suggests that the substitution of bottle for breast has been less important to infant health than other factors such as sanitation, availability of health services, and the education and income of the mother.

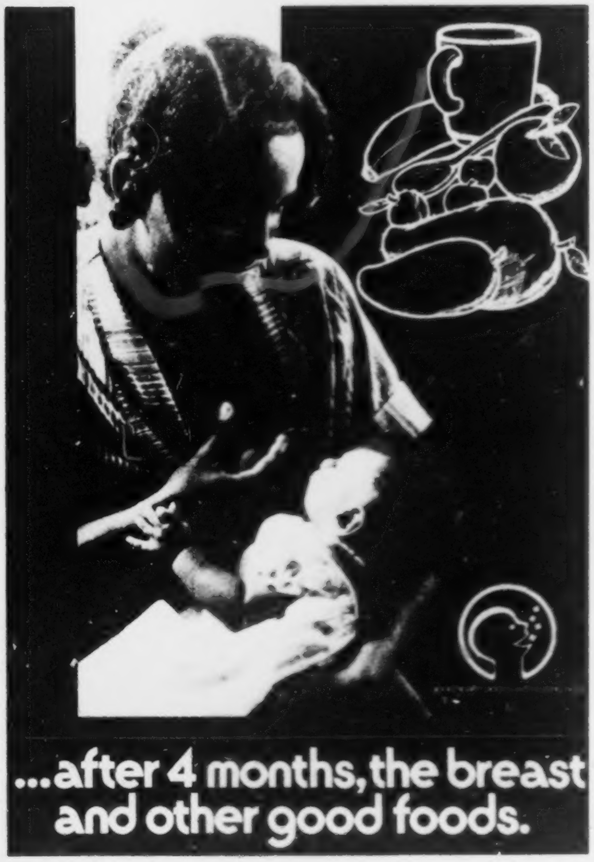
The health risks of bottle-feeding compared with breast-feeding are greatest among the urban and rural poor in developing countries, who may not use commercial preparations correctly. For example, poor women may not know how to prepare commercial infant formula; they may not be able to afford an adequate supply; or they may give infants nonnutritious substitutes. Clean water for washing utensils and mixing with formula is often unavailable, as is fuel for boiling the water or sterilizing the bottles, and refrigeration for storage. Under these conditions bacterial contamination is inevitable (526).

Studies of infant feeding and nutrition among several hundred children in Colombia (616), St. Vincents (23), and Lebanon (293) indicate that breast-fed children are less likely to be malnourished than bottle-fed children, or, in the case of Lebanon, that children who fail to thrive are more likely to be bottle-fed, especially in the first three months of life. Moreover, in St. Vincents early weaning from the breast and introduction of supplementary food before four months resulted in less weight gain than delaying supplementation until after four months (23). When supplementation should begin is uncertain, however (see box, this page).

With respect to illness among children, several studies, including some in developed countries (108, 109, 131, 144, 321), find a lower incidence of infection, especially diarrhea, among breast-fed infants (178, 577, 616). In Colombia, for example, Joe D. Wray and Alfredo Aguirre found that only 25 percent of the exclusively breast-fed children had diarrhea during the first five months of life, compared with 54 percent of the partially bottle-fed and 73 percent of the exclusively bottle-fed children (616). Continued breast-feeding during diarrhea is important not only to maintain food and fluid intake but also to prevent cessation of lactation (see **Population Reports**, *Oral Rehydration Therapy for Childhood Diarrhea*, L-2, November-December 1980). Several other studies in developed and developing countries, however, have found no increased risk of disease in bottle-fed children (15, 134, 147). In Malaysia, for example, a study of 250 children reported similar rates of respiratory and gastrointestinal illness among breast- and bottle-fed babies (134).

### Infant Mortality

A great deal of public health experience suggests that breast-fed children have lower death rates (306, 461, 573, 613), but only a few studies in developing countries have been specifi-


...after 4 months, the breast and other good foods.

**Breast-feeding can be continued for at least two years with nutritional benefit to the child, but WHO/UNICEF expert groups now recommend that food supplementation begin between four and six months, as this poster from Jamaica suggests.** (Ministry of Health)

cally designed to examine mortality and the method of feeding. A study of 1,700 women in rural Chile in 1969 and 1970 found that postneonatal death rates (between the 4th and the 52nd week) were three times higher among infants who started bottle-feeding in the first three months than among those who received only breast milk during that time (440). Because the infants were less likely to be breast-fed, death rates were higher among children whose mothers had moderate education, higher incomes, better sanitation, and prenatal health care than among those without—a contrast with the influence of socioeconomic factors on mortality in most studies.

In a Malaysian study of over 5,500 live-born infants, the risk of dying was significantly greater for infants breast-fed only briefly. The risk of mortality associated with short breast-feeding was substantially less when the infants lived in communities with better water supply and sanitation systems (74).

A recent study in Cairo under the auspices of the International Fertility Research Program found that children who were breast-fed for 15 to 20 months had a 93 percent probability of surviving until the birth of the next child, whereas children never breast-fed or breast-fed for less than three months had a survival probability of about 64 percent (269). Although the educational level of the mother also influenced child survival, the influence of breast-feeding was greater, and the lower the mother's educational level, the more influence breast-feeding had. Among children whose mothers had no education, those breast-fed for 9 to 12 months had a 30 percent higher survival probability than those never breast fed; among children whose mothers had at least seven years of schooling, the difference was 22 percent (269).

This recent evidence is strengthened by historical studies of breast-feeding and infant mortality in Europe and the United States (613). In southern Bavaria in the early part of the 20th century, for example, infant mortality rates were lowest where the proportion of infants breast-fed for at least six months was highest (309).

In the US a cohort study of more than 20,000 infants seen in infant welfare clinics between 1924 and 1929 showed similar results (643). In the first nine months of life bottle-fed babies were over 100 times more likely to die from respiratory disease and over 40 times more likely to die from gastrointestinal disease than breast-fed infants. Mortality rates for partially breast-fed infants were intermediate between the other two groups.

Mortality studies may exaggerate the relative risk of bottle-feeding. Often the deaths of seriously ill infants too weak to suckle or who die before they can breast-feed are counted among the deaths of bottle-feeding infants. In a study in Guatemala, for example, the mortality rates for non-breast-fed infants born between 1969 and 1974 decreased from 386 deaths per 1,000 live births to 208 when infants with health problems preventing breast-feeding were excluded (120). Even when these infants were excluded, however, bottle-fed infants were more than twice as likely to die in infancy as breast-fed infants (120). In a frequently cited study in India, the mortality rate among bottle-fed infants was eight times as high as the rate among breast-fed infants, but half the 20 bottle-fed infants were too weak to breast-feed (178). Research in a society where the reasons for bottle-feeding are not predominantly health problems of the mother or infant would provide a better estimate of the risk of bottle-feeding (120).

While much evidence argues for the importance of breast-feeding in holding down infant mortality rates, in a number of developed countries infant mortality has declined rapidly over the last century even though breast-feeding also has declined. In Sweden, for example, a sharp decline in infant mortality occurred first, followed by a decline in the duration of breast-feeding along with a continued, slower decline in infant mortality (558). This sequence suggests that the trend away from breast-feeding may have slowed, but did not reverse the overall decline in infant mortality. In Thailand infant mortality is lowest in the urban areas and among children of better educated women or urban women with white-collar jobs, who are most likely to stop breast-feeding early (307). As John Knodel and Nibhon Debavalya point out:

> ...although reduced breast-feeding undoubtedly has unfavorable health consequences for children, it does not appear to be a major determinant of infant mortality levels in Thailand. Other factors are apparently more important, including access to modern health services.... Whatever the critical factors are, the fact that infant mortality is at least severalfold higher in the countryside, where prolonged breast-feeding continues to be common, suggests that any significant reduction in the mortality level must stem from improvements in conditions other than breast-feeding practices.... (307)

Nonetheless, a review by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) concluded that in the future a decline in breast-feeding in developing countries might have a serious adverse impact on child health in areas where health and other social services are inadequate (610).

### Other Benefits

A number of other benefits of breast-feeding have been suggested, with varying degrees of proof. These possible benefits for the child include:

- facilitating a close emotional relationship between mother and child (274, 330, 387, 610),
- avoiding dental caries caused by children sleeping with bottles in their mouths (274),
- promoting normal facial development (274, 387),
- avoiding infant obesity (274, 330, 595, 671),
- protecting against various diseases, including coronary heart disease, ulcerative colitis (274, 387), sudden infant death syndrome (196, 274, 595), acute necrotizing enterocolitis, a highly lethal disease of premature infants (595), and multiple sclerosis (129),
- improving speech development (65),
- promoting greater intellectual ability (476, 610).

For the well-nourished woman, breast-feeding helps to restore a slimmer figure by utilizing body fat accumulated during pregnancy and by hastening involution of the uterus. Breast cancer, once thought to be less likely among women who breast-fed, has now been shown to be less likely with a young age at first pregnancy, but not with breast-feeding (350, 654).

### Why Women Stop Breast-Feeding

There are few medical contraindications to breast-feeding by adequately nourished women. There are also no known reasons that full-term infants should not breast-feed (330), but some—premature infants or those with serious congenital abnormalities—may be unable to suckle vigorously enough to obtain milk. Nevertheless, despite evidence of the benefits of breast-feeding, some women prefer not to breast-feed, for a variety of physical and psychological reasons. As a recent WHO brochure points out, "The mother who cannot breast-feed or decides not to do so should not be made to feel guilty" (604).

Breast-feeding may cause some illness or discomfort particularly in the early weeks postpartum. Breast engorgement, sore and cracked nipples, and leakage of breast milk are common complaints which sometimes cause women to stop breast-feeding (see p. J-549). A reduction in vaginal secretions due to low estrogen levels may make coitus uncomfortable. Some women therefore use contraceptive foams or jellies to provide vaginal lubrication as well as protection against pregnancy. More serious conditions—breast abcesses and mastitis—are painful but not generally life-threatening. They require medical care and sometimes antibiotics (330). In women with inadequate diets, repeated pregnancies and lactation can lead to maternal depletion (see box, p. J-528).

Women who do not wish to breast-feed may find it physiologically difficult to do so because the release of breast milk to the infant (the "let down," or milk ejection reflex) depends in part on the mother's ability to relax (274).

As many surveys in both developed and developing countries show, one of the major reasons women give for stopping breast-feeding is insufficient milk (200, 274, 291, 482, 605). Why is insufficient milk such a widespread problem? On one hand, experts in the field contend that virtually all women can produce enough milk for their infants (274, 330, 468). On the other hand, there is empirical evidence that some women do have difficulty breast-feeding and that many infants, especially *among the poor in developing countries, do not thrive on* breast milk alone (9, 38, 91, 176, 213, 571, 614). Insufficient milk is reported in affluent as well as poor communities, however (200). For example, in the WHO Collaborative Study on Breast-feeding, conducted in seven developing and two developed countries, 70 percent of the Hungarian women who had stopped breast-feeding said that they did so because of insufficient milk. In Guatemala 60 percent of the affluent urban women cited insufficient milk compared with 44 percent of the urban poor women and 28 percent of the rural women (605).

The claim of insufficient milk covers a variety of problems ranging from genuine maternal ill health or severe malnutrition to improper feeding techniques, faltering growth or illness on the part of the infant, early introduction of other foods, and lack of confidence, as well as a personal preference not to breast-feed. Some of these problems are poorly understood or cannot be resolved. Often, however, a lack of support and proper information may be the real reasons that women have problems breast-feeding.

In societies where breasts are seen primarily as sexual and erotic, the function of breast-feeding may seem awkward and embarrassing (46, 330), and women may be uncomfortable nursing their infants in public. Women may also be concerned that breast-feeding will change the shape and size of the breasts, although this has not been proven. Leakage of breast milk during sexual intercourse and at other times until the let down reflex is well established may also be disturbing.

Inherent in breast-feeding is the continued heavy reliance of the infant on the mother. The mother's body must continue to provide nutritional support for the infant, as it did during pregnancy. Also, a woman who is fully breast-feeding cannot leave the infant for more than very short periods. Thus breast-feeding limits a woman's ability to move about without bringing the infant along. At the same time, breast-feeding diminishes the opportunities for the father or others to share in feeding the child. These disadvantages become particularly apparent in urban areas where jobs tend to be incompatible with full breast-feeding and where women have opportunities to be active outside the home.

## BREAST-FEEDING PATTERNS AND TRENDS

Current research has focused on three different aspects of breast-feeding:

1. the percentage of infants who breast-feed initially,
2. the average duration of breast-feeding, and
3. the type of breast-feeding—described in terms of scheduled or on-demand feeding, with or without night feeding, with or without other foods, frequency of suckling, or intensity of suckling.

The vast majority of women in developing countries breast-feed their infants initially, although the percentages are slightly higher in Africa and Asia than in Latin America and the Caribbean (see Figure 1). In all 4 African countries and in 7 of 12 Asian and Middle Eastern countries where World Fertility Surveys (WFS) have been taken, more than 90 percent of women whose last child was born within the five years preceding the survey initially breast-fed that child. In 8 of 12 Latin American and Caribbean countries over 85 percent of last children were breast-fed (150). Even in the four countries with the lowest percentage breast-feeding—Malaysia, Costa Rica, Panama, *and Trinidad and Tobago—between 70 and 80 percent breast-*fed initially.

The recent World Health Organization (WHO) Collaborative Study on Breast-feeding produced similar results, although the various socioeconomic groups studied were not nationally representative. In seven of the nine countries more than 90 percent of the women's youngest infants had been initially breast-fed in all socioeconomic groups. In two of the three participating African countries—Nigeria and Zaire—virtually all infants were breast-fed initially (605).

The duration of breast-feeding is longer in Africa and Asia than in Latin America and the Caribbean (see Figure 1). In the four African countries with WFS data, children are breast-fed for a median of at least 16 months. Among 12 Asian and Middle Eastern countries the median length of breast-feeding ranges from a low of 3 months in Malaysia to a high of 31 months in Bangladesh. In 7 of these 12 countries mothers breast-feed their children on average for 16 months or more. In 12 countries of Latin America and the Caribbean, however, median duration of breast-feeding ranges from 2 months in Costa Rica to 15 months in Haiti (150). These calculations of the length of breast-feeding are based on the ages of children who were being breast-fed at the time their mothers were interviewed (150). Analyses of survey data, like all analyses of breast-feeding patterns and trends, have methodological short-comings (424) (see box, p. J-538). Nonetheless, these data are the best current indicators of the extent of breast-feeding in these countries.

Another way to measure the duration of breast-feeding is by finding the percentage of women still breast-feeding at designated intervals after delivery—for example, at six months (444). In 9 of 10 Asian and Middle Eastern countries reporting WFS data, 70 percent or more of 6-month-old infants were still being breast-fed (148, 444) (see Figure 2). In Latin America and the Caribbean, however, many have stopped breast-feeding by six months. Among seven of eight Western Hemisphere countries surveyed, the percentage of 6-month-old infants still being breast-fed was between 35 and 60 percent (148) (see Figure 2).

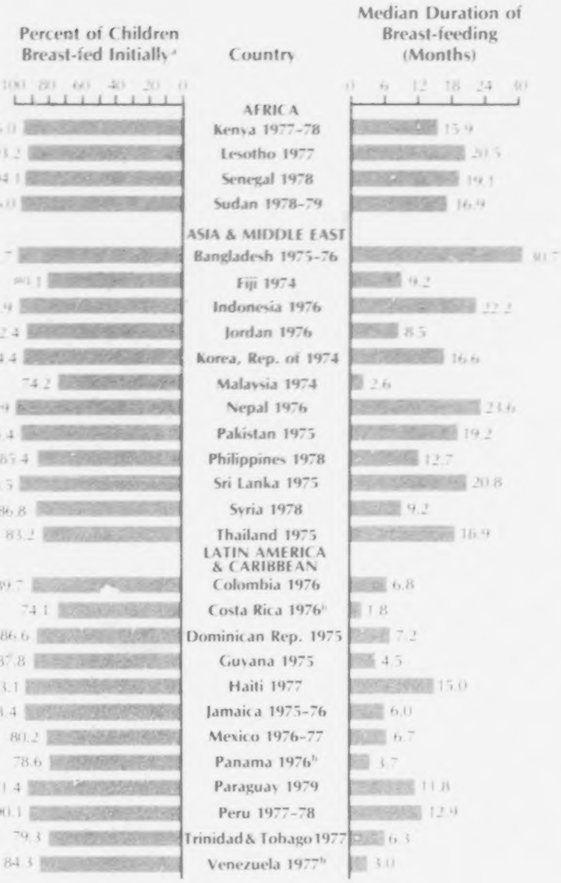
### Variation in Suckling and Feeding

Breast-feeding can also be measured by suckling frequency, amount of time infants spend suckling, and the extent to which they receive other foods. Since the contraceptive protection of breast-feeding is strongly influenced by the amount of suckling (see pp. J-542–543), it is important to take account of suckling patterns, influences on them, and the ways that they change over time.

The WHO Collaborative Study on Breast-feeding reports a wide variation in suckling patterns in the nine countries examined. During the first six months most mothers who breast-fed did so "on demand," that is, depending on the infant's wants. Feeding on demand, however, ranged from frequent, irregularly timed suckling episodes to feedings approximately every three to four hours. The proportion of women feeding on a schedule rather than on demand was generally higher among urban residents, particularly wealthy ones, than among rural residents (605).

In the first three months of life infants were fed an average of five to seven times during waking hours and two or three times at night. Generally, infants of rural poor women suckled most often, and infants of urban, upper-income women, least often. Among the urban middle- and upper-income groups, the number of daytime feedings dropped steadily as the infants grew older, but among the rural poor most of the 15- to 17-month-old infants still nursing were nursing four or more times during the day (605). Other studies of breast-feeding, especially in rural Africa, report an average of 13 or more feedings per day, including night feedings, for up to 2 years (227, 315). In the WHO study, night feeding of older infants was a common practice in all seven developing countries studied, but in the two developed countries—Hungary and Sweden—most breast-feeding mothers had stopped night feedings by the time the infant was six months old (605).

**Figure 1. Percentage of Children Breast-Fed Initially and Duration of Breast-Feeding in 28 Developing Countries, World Fertility Survey Data**



[a] For children born in the five years preceding the survey

[b] Women age 20–49

Source: Ferry & Smith (150)

**While the percentage of children initially breast-fed is high in all 28 developing countries reporting World Fertility Survey data (left side of graph), the median duration of breast-feeding varies considerably, ranging from over 30 months in Bangladesh to less than two months in Costa Rica (right side of graph).**

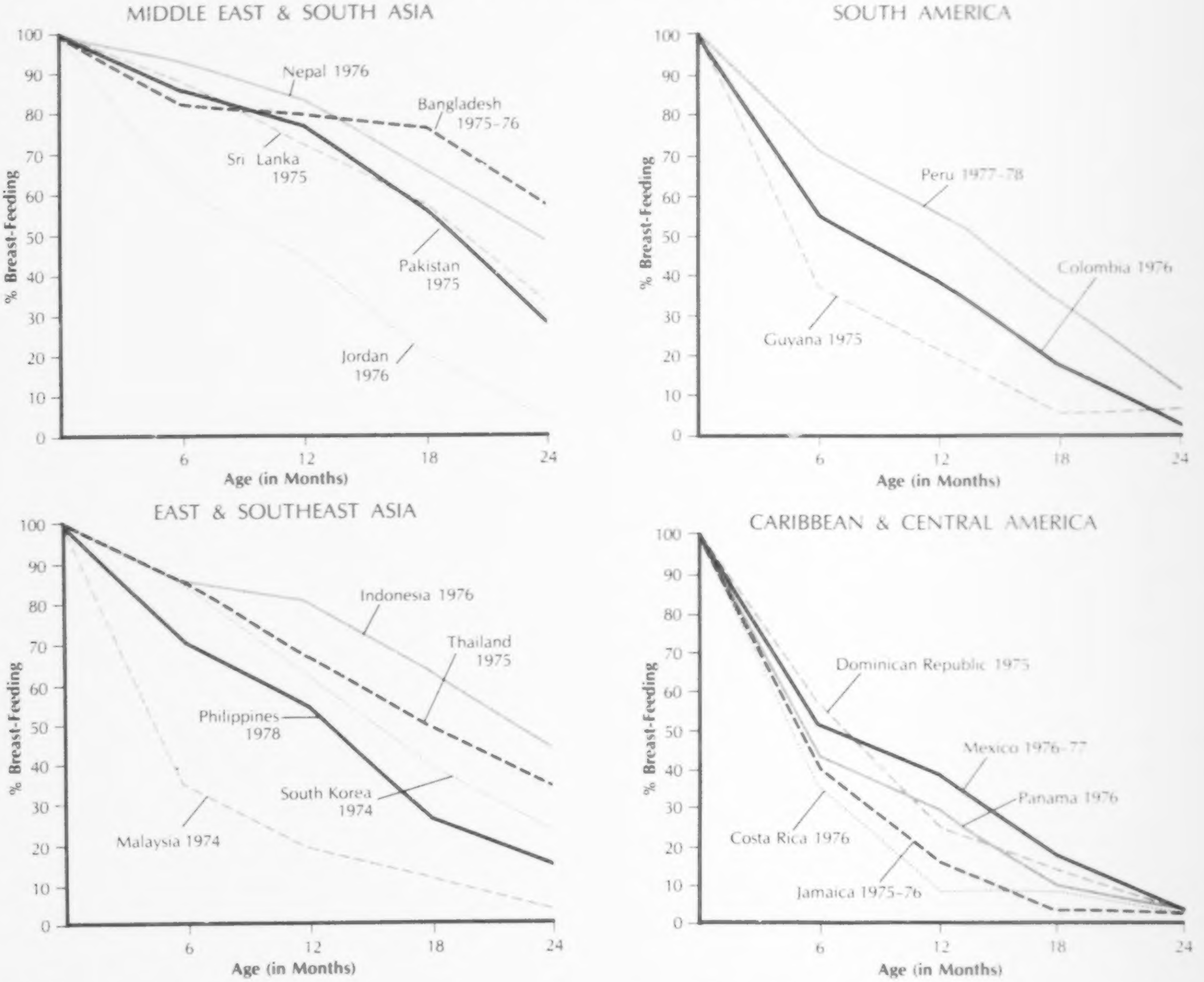
By three months, more than one-third of the infants in most of the WHO groups had been given supplementary feedings, usually milk and milk-based products, although the variety of foods was wide. By six months, at least two-thirds of the infants in most study groups received regular supplementation, and by one year supplementary feeding was almost universal (605). Many studies in different countries report that mixed feeding of breast milk and supplementary food beginning in the early weeks postpartum is a common practice (3, 23, 73, 128, 199, 227, 303, 351, 355, 380, 384, 395, 466, 513, 577). By contrast, in some areas, such as rural India, children are exclusively breast-fed well beyond six months (354, 605), when, it is generally agreed, supplementation should begin (see box, p. J-530).

### Breast-Feeding Trends

An increasing amount of evidence suggests that fewer women in the developing world now initiate breast-feeding and those who breast-feed continue for shorter periods. This has caused growing concern among health professionals (32, 47, 89, 189, 274, 405, 435, 446). Concern about breast-feeding trends is not new. Medical writers for centuries have noted the importance of breast-feeding to infant health and have lamented the failure of upper-class women to breast-feed their own children (587). The use of wet nurses was common among the upper classes in ancient Greece and later in Europe long before commercially manufactured infant formulas became available (586). At about the time of the industrial revolution in the 19th century, breast-feeding began to decline among women of all classes in the European countries (588, 589).

In the last three decades, the practice of breast-feeding seems to be declining in many developing countries throughout the world. The best statistical evidence of declines comes from five countries where samples representative of the national population have been studied—South Korea (101), Thailand (307), Malaysia (73), Taiwan (382), and Mexico (380). In Thailand,

**Figure 2. Percentage of Women Initiating Breast-Feeding Who Continue to Breast-Feed, by Infant's Age, in Developing Countries, World Fertility Survey Data**



Note: Plotted points are based on the sums of numerators and denominators for the month preceding and the month following as well as for the indicated month. For example, the percentage plotted at six months is based on data for five, six and seven months.

Source: Ferry (148)

**The duration of breast-feeding can be measured by the percentage of women initially breast-feeding who are continuing to breast-feed at specified intervals after delivery. At 12 months, more than half of these women are still breast-feeding in 8 of 10 Asian and Middle Eastern countries (graphs on left) but in only one of 8 Latin American and Caribbean countries (graphs on right).**

Taiwan, and Mexico, several consecutive surveys were taken, thus minimizing memory errors. In Malaysia and South Korea, information came from personal life histories.

In South Korea the practice of prolonged breast-feeding—for at least 18 months—declined sharply between 1950 and 1970, from over 55 to about 35 percent of first births. There was only a slight decrease, however, in the percentage of first-born infants breast-fed at least one year, which remained above 75 (101).

In Thailand between 1969 and 1979 the average duration of breast-feeding declined by almost five months—from 12.9 to 8.4 months in the cities and from 22.4 to 17.5 months in rural areas. As in South Korea, there appears to have been little change in the proportion breast-feeding initially (307).

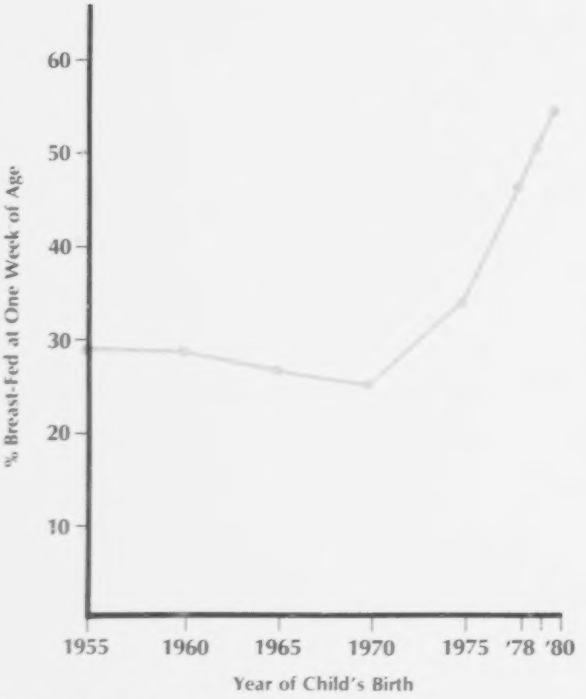
In Malaysia, on the other hand, from before 1960 to 1974 there was a drop both in the percentage breast-feeding initially and the duration of breast-feeding. The percentage of infants breast-fed initially dropped from 89 to 74 percent and the percentage breast-fed for more than three months decreased from 75 to 53 percent. The changes have been greater among ethnic Indians and Chinese than among ethnic Malays. There has also been a decline in the age at which supplementary foods are introduced (73).

In Taiwan also, the percentage of infants initially breast-fed fell sharply, from 93 in 1966 to 50 in 1980. During the same period the average duration of breast-feeding of children ever breast-fed dropped from 14.6 months to 8.8 months (382).

In Latin America national breast-feeding trends over long periods of time are not available. In Mexico the percentage of last liveborn infants initially breast-fed dipped from 80 to 78 percent in the 3-year period 1973 to 1976 (380). Whether this decline will continue is not clear. Recent Contraceptive Prevalence Surveys in other Latin American countries, however, suggest that breast-feeding has declined substantially. Less than 5 percent of the women surveyed in the cities of São Paulo (Brazil), Panama City (Panama), and San Salvador (El Salvador) breast-fed for six months or more, and in the state of São Paulo, Brazil, less than 50 percent breast-fed for as long as one month (392).

Other evidence of declines in breast-feeding comes from community health studies, repeated but not always comparable surveys, review of data from specific health care centers, and the clinical impressions of people with long experience in child health programs in developing countries. While this information may be questionable from an epidemiological point of view, it all points toward a considerable decline in breast-feeding, especially in urban areas. For example, among upper- and lower-income ethnic Chinese in Singapore, in 1951, 85 and 90 percent of infants, respectively, were initially breast-fed; in 1971, 28 and 51 percent were breast-fed. While in 1951 some 45 percent of infants among the poor and 77 percent among the wealthy were still breast-fed at three months, by 1971 about 5 percent in either group were (681). Among the Baganda people of Uganda the proportion of infants attending child welfare clinics who received supplementary bottle-feeding before six months of age rose from 14 to 30 percent between 1950 and 1955, although the duration of lactation did not change (577). According to surveys of outpatient clients in southern Brazil, in 1940 some 98 percent of infants were initially breast-fed; in 1974, 76 percent. During the same period the percentage still fully breast-fed at six months fell from 68 to 12 (670). Studies of groups as varied as Micronesian villagers (357) and Canadian Eskimos (495) found that the more recently a child was born, the more likely the child was to be partially or entirely bottle-fed.

**Figure 3. Percentage of Infants Breast-Fed at One Week of Age, United States, 1955–1980**



Source: Martinez et al. (360)

**In the US, the percentage of infants being breast-fed at one week of age is rising sharply after declining for several decades. Increases in initial breast-feeding are also reported in Sweden and Australia.**

By contrast, in some developed countries the practice of breast-feeding is now increasing after several decades of decline. In the United States the percentage initially breast-feeding has been rising since the early 1970s. After declining to 22 percent in 1972 in one set of surveys, it rose to 34 in 1975 (225, 233). In another set of surveys, the percentage initially breast-feeding declined to 25 percent in 1970, rose to 33 percent in 1975, and to 54 percent in 1980 (360) (see Figure 3). The latter surveys show that between the years 1955 and 1980, while the percentage initially breast-feeding dropped and then rose, the percentage initially receiving infant formulas rose steadily, and the percentage receiving evaporated milk and cow's milk dropped dramatically (360). Concerning the duration of lactation, in 1971 only 5 percent of infants were still being breast-fed at ages five and six months; in 1980, 25 percent (360, 361).

Increases in breast-feeding have been reported in other developed areas as well. For example, in Sweden official statistics show that between 1972 and 1975 the percentage of infants fully breast-fed at two months of age rose from 31 to 46 percent; at six months of age, from 6 to 14 percent (235, 558). At infant welfare centers in Victoria, Australia, the percentage of infants breast-fed at three months rose from about 20 in 1972 to 38 in 1977 (515, 593). In a suburb of Sidney, Australia, the percentage breast-feeding at six months rose from 12 in 1972 to 48 in 1977 (332).

### Sociodemographic Factors

Breast-feeding patterns in developing and developed countries may be influenced by many sociodemographic factors, including:

- place of residence—rural or urban
- education and socioeconomic status of the parents
- mother's age and parity
- support from family and friends
- employment of the mother
- use of contraception.

Many of these sociodemographic factors are closely related, making analysis difficult. For example, the urban woman is more likely to be well-educated, employed, relatively isolated from her extended family, younger, and with fewer children. Therefore, as a study looks at one factor, it must take others into account; this can be done statistically. Even more difficult is identifying and accounting for a large number of possible influencing factors. For example, in an 8-country study the seven common sociodemographic factors studied together explained only between 6 and 32 percent of the variation in breast-feeding duration (265) (see Table 1).

Of the factors studied to date, urban-rural residence seems to have the most consistent effect. In all developing countries for which data are available, rural women are more likely to breast-feed than urban women (19, 73, 132, 265, 284, 301, 307, 380, 444, 505, 524, 557, 567, 577, 605). While urban-rural differences are pervasive, they are not always large, particularly in Africa (444, 605). According to WFS data, in many countries the difference in the proportions that breast feed initially is slight, but urban women breast-feed for markedly shorter periods. For example, among rural infants, more than half were still breast-feeding at six months in seven of eight Latin American and Caribbean countries, while among urban infants in only one country—Peru—were more than half still breast-feeding at six months (444). In Thailand, Jordan, and Pakistan studies have found that women who had always lived in rural areas breast-fed the longest; women who had always lived in urban areas breast-fed the shortest; and those who had moved from rural to urban areas breast-fed for an intermediate period (307, 505, 628). In Thailand, Jordan, and Taiwan breast-feeding was more likely in smaller cities than in larger cities and more likely in rural areas that were farther from urban centers (307, 382, 628). In the three Asian countries for which nationally representative data on urban-rural trends are available, breast-feeding duration has declined in both urban and rural areas (73, 307, 382).

In developing countries, the better educated a women and the higher her socioeconomic status, the less likely she is to start breast-feeding, and, if she starts, on average she breast-feeds for a shorter period. This pattern has been seen in about two dozen countries (19, 30, 132, 284, 301, 380, 382, 395, 406, 423, 442, 577, 605). The associations seen between residence, education, and socioeconomic status, on one hand, and the extent of breast-feeding, on the other, cannot be proved to be causal from these studies (70). Nonetheless, the associations suggest that, as urbanization, education, and standard of living increase, the overall practice of breast-feeding will decline unless other changes counteract them.

**Table 1. Association of Selected Sociodemographic Factors with Duration of Breast-Feeding for the Next-to-Last Child, World Fertility Survey Data for Eight Countries**

**+ = statistically significant positive association**
**0 = no association**
**– = statistically significant negative association**

| | Bangladesh | Indonesia | Jordan | Sri Lanka | Colombia | Guyana | Panama | Peru |
|---|---|---|---|---|---|---|---|---|
| **Older age** | + | + | + | 0 | + | 0 | 0 | + |
| **Higher parity** | – | – | 0 | 0 | 0 | 0 | 0 | 0 |
| **Better educated mother** | – | – | – | – | – | – | – | – |
| **Urban residence** | – | – | – | – | – | – | – | – |
| **Male child** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Mother employed since marriage** | 0 | 0 | 0 | 0 | 0 | 0 | – | 0 |
| **Death of breast-feeding infant** | – | – | – | – | – | – | – | – |
| **% of variation explained by these variables** | 5.7 | 31.6 | 12.3 | 12.2 | 13.7 | 5.9 | 19.3 | 26.2 |

Source: Jain & Bongaarts (265)

By contrast, in some developed countries, including the US and Sweden, breast-feeding is now more common among highly educated women (104, 233, 235, 360, 512, 514, 605). In the US, college-educated women are most likely to start breast-feeding and to breast-feed for longer durations; women who attended no more than high school are least likely to breast-feed; and women with still less education are between the other two groups (233).

Once other factors are taken into account, there is no consistent relationship among countries between a mother's age or the number of previous children and the likelihood that she will breast-feed. In some countries older women are more likely to breast-feed, and for longer durations, but this is not always the case (19, 73, 148, 225, 233, 265, 301, 380, 512, 605). Individual women often seem to follow the same breast-feeding pattern for each of their children. Thus, if a mother breast-fed a previous child, particularly if she breast-fed for a relatively long time, she is much more likely to breast-feed her current infant for a long time (97, 138, 233, 579, 605). Despite the apparently widespread preference for sons, boys generally are not breast-fed longer (19, 148, 265, 382, 403). In South Korea and Jordan, however, boys are somewhat more likely to be breast-fed initially (403, 628).

A woman's family situation and friends influence both her ability and her desire to breast-feed (3, 19, 73, 272, 274, 285, 364, 382, 442, 468, 528, 557, 610). Women who have breast-fed provide the new mother with models to emulate and advise her how to breast-feed successfully. Members of the household may help a woman breast-feed soon after childbirth by doing household chores or by earning an income for the family. Several studies have shown that, when older children, adult relatives, or servants are present, women are more likely to breast-feed initially and, in some cases, longer (19, 73, 382, 442). Their presence, however, can also lead to earlier supplementation and an earlier end to breast-feeding (73, 442, 557), suggesting that they may also help with supplementary feeding.

### Influence of Employment

Does a woman's employment affect her breast-feeding? Logically, the location of the woman's workplace and her child care arrangements cannot fail to affect her opportunities to breast-feed. Nonetheless, evidence on the link between working and breast-feeding practice is not clear (19, 233, 279, 307, 442, 443, 445, 557, 561). The fact that women in surveys do not often cite "employment" as a reason for not breast-feeding (561) should not be considered conclusive, since women also rarely mention urban residence, advertising, or the advice of friends or health personnel as reasons for not breast-feeding (70).

Often the results of studies depend on how work is defined and where it is performed. In an analysis of WFS data from eight countries, whether a woman worked and where she worked were generally not associated with breast-feeding duration, but "work" included any work since marriage and appeared to have been interpreted differently in different countries (265). Further analysis of data for two of these countries—Jordan and Sri Lanka—shows, however, that women who worked outside the home when their children were young were less likely to breast-feed (19, 628). In Taiwan women employed outside the home were less likely to breast-feed than either housewives or women who worked at home for pay (382). In Malaysia women who work for wages are less likely to breast-feed, and those who earn the highest wages breast-feed the least (73). In Thailand breast-feeding does not seem to be much influenced by a woman's place of work, employer, or whether she receives wages, but, among those employed, white-collar workers breast-feed the least (307). In the US, occupation does not seem to have a strong influence on breast-feeding (233). Overall, agricultural employment, which is the usual role for women in traditional societies, is more likely to be associated with prolonged breast-feeding than any other type of employment or remaining home without other work (73, 307).

### Contraceptive Use

In general, women who use modern contraceptives are less likely to breast-feed than women who do not use modern contraceptives (19, 73, 307, 340, 382, 505, 626, 625, 628). Furthermore, when contraceptive users do breast-feed, the duration of breast-feeding is likely to be several months shorter. Where different contraceptive methods have been compared, women who use oral contraceptives are less likely to breast-feed or

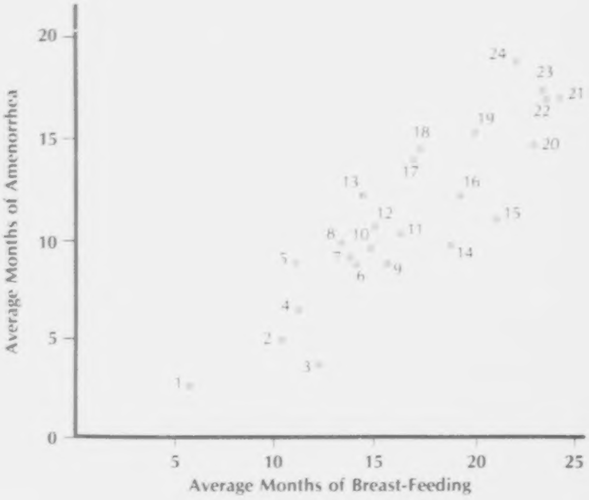
**Agricultural work is not incompatible with breast-feeding, and in some parts of Africa women breast-feed for up to three years.**

**Urban women who work outside the home or in white-collar or well paid jobs are less likely to breast-feed than rural women.** (ILO) breast-feed for a shorter period than women using other methods (307, 420, 625, 653).

Because breast-feeding depends on both deliberate choices and physiological reactions, it is often not clear from information available in surveys exactly what determines the duration of breast-feeding. One possibility is that women who use modern contraception, like those who curtail breast-feeding, tend to be predominantly urban, better educated, and from middle- or upper-income groups (see **Population Reports,** *The World Fertility Survey,* M-3, July 1979, and **Population Reports,** *Contraceptive Prevalence Surveys: A New Source of Family Planning Data,* M-5, May–June 1981.) Their socioeconomic situations may independently influence both breast-feeding and contraceptive use. Another possibility is that women who breast-feed for shorter periods need to adopt effective contraception earlier in order to assure a reasonable interval between pregnancies. Still others may be substituting the more certain protection against pregnancy that modern contraceptives provide for the traditional protection of breast-feeding (307, 625), which grows increasingly unreliable as breast-feeding continues (see pp. J-539–541).

Still, there are exceptions. In Thailand and South Korea contraceptive users who want no more children breast-feed longer than users who want more children (307, 403). These women apparently welcome the double protection of breast-feeding and contraceptives. Also, some women may use contraceptives to be sure that breast-feeding is not interrupted by another pregnancy. In the Philippines, for example, IUD users have lower pregnancy rates and breast-feed longer than women who use other methods or who use no method (420, 422). In Ghana IUD users have the longest birth intervals and breast-feed the longest, and users of hormonal contraceptives also have longer birth intervals and breast-feed longer than women who use no contraception, although not as long as IUD users (653).

**Figure 4. Average Durations of Breast-Feeding and Amenorrhea for Various Populations**



**When various groups are compared, it is clear that the longer the average length of breast-feeding, the longer the average length of amenorrhea. When breast-feeding is prolonged, menses tend to resume before the end of breast-feeding.**

## PROBLEMS IN STUDYING BREAST-FEEDING PATTERNS

Breast-feeding depends on the interaction of personal motivation and the physiology of lactation—both complex processes that are not fully understood. Thus many methodological problems arise in studying breast-feeding behavior by surveys. These problems include:

- Some surveys study large, randomly selected groups but often without sufficient detail, while more detailed studies of smaller groups are often not representative of the whole population.
- A complete description of breast-feeding requires information on the frequency and duration of infant suckling and on the frequency and types of supplementary foods provided. This information is difficult to gather in surveys.
- When data are gathered retrospectively, women may make errors or give round numbers when recalling breast-feeding experience. For example, women often report breast-feeding duration as a multiple of six months, but other evidence suggests that cessation of breast-feeding is usually more gradual (148, 163, 307, 406, 340).
- Most women know that breast-feeding is better for the infant than bottle-feeding (605) and so may report breast-feeding that did not take place because they think that interviewers favor breast-feeding (270).
- Analyses of survey data may yield very different results depending on whether only last births, only next-to-last births, or all births within a given number of years are considered. For example, the choice of which births to analyze makes a 6-month difference in the estimated duration of breast-feeding calculated from World Fertility Survey data for Pakistan (426).
- Whether infants who die are included in the analysis affects the results, particularly if there is a high infant mortality rate.

Because of these problems, much of the survey research to date has been incomplete, biased, or inconclusive (102, 202, 203, 339, 424, 426, 516). Although certain overall patterns are evident, many conclusions are still tentative and country-specific.

**Key to Figure 4**

| No. | Population & Ref. No. | No. | Population & Ref. No. |
|---|---|---|---|
| 1 | urban Nigeria—women with secondary education (340) | 11 | US—self-selected (304) |
| 2 | urban Nigeria—women with primary education (340) | 12 | Taiwan—national sample (268) |
| 3 | urban Iran (508) | 13 | Ghana—national sample (163) |
| 4 | India—university clinic patients (619) | 14 | urban Senegal (149) |
| 5 | rural Philippines—IUD acceptors (421) | 15 | rural India (450) |
| 6 | rural Yemen (399) | 16 | urban Senegal (149) |
| 7 | rural Nigeria—next-to-last births (576) | 17 | rural Guatemala (118) |
| 8 | rural Nigeria—last births (576) | 18 | rural Zaire (86) |
| 9 | urban Nigeria—women with no education (340) | 19 | semiurban Senegal (149) |
| 10 | urban Zaire (86) | 20 | US—self-selected, feeding on demand (304) |
|  |  | 21 | rural Bangladesh (94) |
|  |  | 22 | rural Togo (343) |
|  |  | 23 | rural Senegal (149) |
|  |  | 24 | rural Zaire (86) |

Survey data from Thailand (307), Ghana (653), Lebanon (482, 625, 626), and the Philippines (420) show that oral contraceptive users breast-feed for several months less than women who use IUDs or other contraceptive methods. This may mean that the hormones in oral contraceptives have a physiological effect in reducing lactation, as some clinical studies suggest (see pp. J-545–546). Alternatively, it may mean that women who are ready to stop breast-feeding prefer a highly effective method of avoiding pregnancy. Other possibilities are that program policies discourage the distribution of pills to breast-feeding women, which forces women who want the pill to stop breast-feeding (479, 481), or that women are concerned that oral contraceptives may adversely affect the infant and therefore stop breast-feeding when they start to use the pill. Again, on the basis of the available evidence, it is difficult to distinguish the effects of physiological changes from deliberate decisions about breast-feeding and contraceptive use.

Overall, fertility is lowest where contraceptive use is highest (392, 416). Where fertility is high and contraceptive usage low, however, breast-feeding is the principal factor that determines the birth interval length (55). In these areas a major reason for stopping breast-feeding is not the use of contraception but rather another pregnancy (30, 105, 167, 170, 201, 242, 274, 291, 336, 406, 407, 482, 529, 530, 605) Thus contraception can either substitute for or prolong breast-feeding, depending on individual circumstances and motivation.

## IMPACT OF BREAST-FEEDING ON FERTILITY

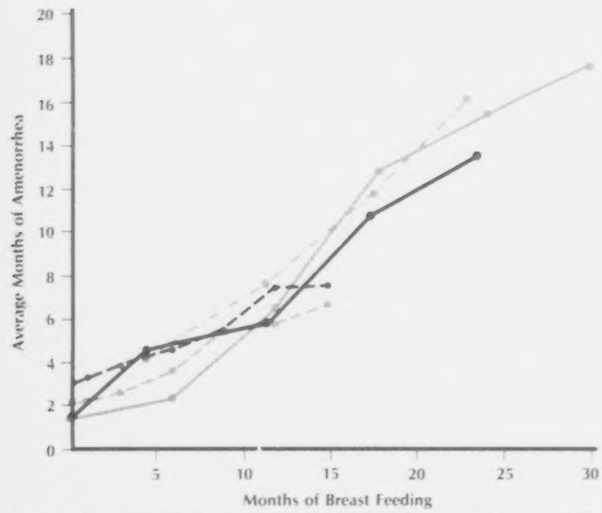
Breast-feeding delays menstruation, inhibits ovulation, and therefore reduces the likelihood of conception. In general, the longer a woman breast-feeds, the longer she will remain infecund. Although the contraceptive effect of lactation has been recognized by various cultures for centuries—at least since the ancient Egyptians (647)—only during the last few decades have biological scientists and demographers focused attention specifically on the length, variations, implications, and causes of lactational infecundity. The overall conclusion is that breast-feeding makes a substantial contribution to birth spacing and fertility control in many areas (668), but that for an individual woman it is an unreliable method of family planning.

Recent research has looked in detail at the relationships between breast-feeding and

- resumption of menstruation,
- resumption of ovulation,
- birth intervals or subsequent pregnancy.

Studies from many parts of the world show a positive relationship between the duration of breast-feeding and the length of postpartum amenorrhea, as illustrated in Figures 4 and 5. Figure 4 compares average duration of breast-feeding and average duration of amenorrhea in different groups of women. For example, urban Nigerian women with primary education (point 2) and clients at an Indian university clinic (point 3) breast-feed for an average of about 11 months and experience amenorrhea averaging 5 and 6 months, respectively. In rural Senegal, where breast-feeding averages over 23 months, amenorrhea lasts almost 18 months (point 23). The relationship is least consistent among groups where breast-feeding is either relatively short—12 months or less—or relatively long—over 20 months. In the intermediate range, however, each additional month of breast-feeding means an average of almost one additional month of amenorrhea (72, 267, 268, 339, 433, 434, 564). Figure 5 shows the length of amenorrhea for women within populations according to the length of time

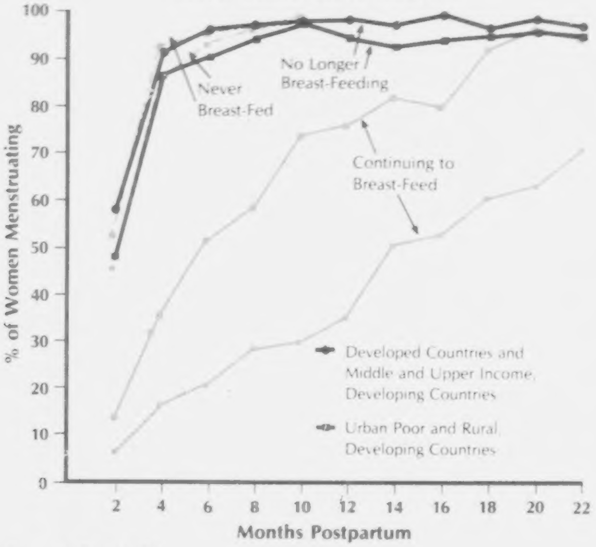
**Figure 5. Average Duration of Amenorrhea by Duration of Breast-Feeding in Selected Populations**



Sources: Bongaarts (55), Cantrelle & Ferry (83), Cantrelle et al. (84), Sivin (510)

**Within a group of women, those who breast-feed for a shorter period experience shorter amenorrhea. In the groups shown, each represented by a line, women who do not breast-feed at all experience amenorrhea lasting one to three months, while for women who breast-feed about 18 months, it lasts 8 to 13 months.**

**Figure 6. Percentage of Women Menstruating by Months Postpartum According to Breast-Feeding Status, WHO Collaborative Study**



Source: Billewicz (51)

**Among women who breast-feed, the percentage who have resumed menstruating increases gradually with time since delivery (solid red lines). Among women who stop breast-feeding (black lines) or who never breast-feed (dashed red lines), almost all menstruate immediately if they are four or more months postpartum.**

**Insuring adequate milk production and also delaying the return of fertility depend primarily on how often and how long the infant suckles and very little on the mother's age, parity, or nutrition.** (WHO/J. Mohr)

each woman breast-feeds. The longer a woman breast-feeds, the longer her amenorrhea lasts. For example, while women in these populations who do not breast-feed at all will average one to three months of amenorrhea, women who breast-feed for 18 months will experience amenorrhea lasting 8 to 13 months.

This relationship can be examined in more detail by comparing breast-feeding women, women who once breast-fed but have stopped, and women who have never breast-fed. At a specified number of months postpartum, what percentage of each group will have resumed menstruation? Figure 6, based on data from the WHO 9-country study, shows that by four months postpartum almost all women who are not breast-feeding are menstruating, whether they ever breast-fed or not. For women who continue to breast-feed, menstruation resumes much more slowly (51).

As Figures 4, 5, and 6 all show, there is considerable variation in these relationships among different groups of women. Some of the variation in Figures 4, 5, and 6 is the result of differences in study methodology (57, 219, 362, 424), but some is the result of actual differences in the groups studied. For example, in Figure 6, using data from the same study, at the same time postpartum a much higher percentage of the urban poor and rural developing country women remain amenorrheic than of the more affluent developing country women and the developed country women (51). The cause of this variation is still being researched and debated but is generally thought to be due to different patterns of suckling (see p. J-542).

### Ovulation and Infecundity During Breast-Feeding

The start of ovulation among breast-feeding women is obviously much more difficult to measure than the start of menstruation. Accurate methods of detecting ovulation are tedious or expensive, while simpler methods are inaccurate. Thus, studies on resumption of ovulation are few and small, with widely varying results. They focus on ascertaining how often ovulation precedes menstruation and under what conditions. This is a matter of practical concern to family planning programs because, when ovulation takes place before menstruation, women may be at risk of becoming pregnant again before they realize they are fecund and so start contraception.

In eight studies the percentage of breast-feeding women identified as ovulating before first menses ranged from 12 to 78 percent (107, 111, 433, 434, 459, 655, 674, 675, 677). In general, the longer the time since delivery, the more likely ovulation is to precede menstruation (434, 638). For example, in a Chilean study by Alfredo Perez and colleagues, ovulation before first menses occurred in 84 percent when menses resumed 60 or more days postpartum compared with 52 percent when it resumed between 30 and 59 days postpartum. Breast-feeding status made a difference, however. Whether menses resumed 30–59 days or 60 days or more postpartum, ovulation before first menses was most likely in non-breast-feeding women, intermediate in partially breast-feeding women, and least likely in fully breast-feeding women (434).

Another way to measure how frequently ovulation precedes menstruation is to identify pregnancies that occur during amenorrhea. In the groups surveyed by the WHO Collaborative Study on Breast-feeding, one to 11 percent of the pregnant women said that they had conceived during amenorrhea (605). In other, prospective studies, between none and 19 percent of women conceived during postpartum amenorrhea, with most studies reporting between one and 10 percent (49, 61, 94, 146, 220, 242, 266, 292, 304, 433, 434, 459, 489, 536, 564, 617). Some of the women were using contraceptives; without contraception, the percentages might have been higher. In groups with little or no contraceptive use, from 3 to 9 percent of women are reported to have become pregnant during postpartum amenorrhea (94, 266, 536).

Even after first menses, some breast-feeding women do not ovulate regularly in the early cycles. In a prospective study of an average of three early cycles after first menses in 134 Chilean women, 43 percent of cycles were apparently anovulatory in the fully breast-feeding women compared with 14 percent in partially breast-feeding women and 9 percent in non-breast-feeding women (663). In a study in Zaire 80 percent of 56 breast-feeding, menstruating women did not ovulate in the cycle studied, compared with 39 percent of 56 non-breast-feeding, regularly menstruating women (123). Other evidence that early cycles after first menses may be anovulatory is that a high proportion of cycles are irregular (49, 508).

Even in early cycles that are ovulatory, whether before or after first menses, a woman may be at less risk of pregnancy than later. Necessary physiologic processes other than ovulation, such as development of the endometrium or the corpus luteum, may not yet be adequate to sustain pregnancy (192, 376, 434, 536, 674).

Whether because of anovulatory cycles or other irregularities in reproductive functioning, lower fecundity after first menses among breast-feeding women is suggested by a comparison of pregnancy rates among noncontracepting Alaskan Eskimos. Twelve months after the first postpartum menses, the life-table pregnancy rate was 60 among breast-feeding women and 81 among non-breast-feeding women (49). Similarly, among noncontracepting women in Taiwan, the likelihood of pregnancy within 12 months after menstruation resumed was 68 percent for those who continued to breast-feed and 80 percent for those who stopped breast-feeding before menstruation resumed (266).

### Effects of Shorter Breast-Feeding on Fertility

Because the length of breast-feeding and the length of postpartum infecundity are linked, any substantial shortening of the average duration of breast-feeding will lead to higher fertility unless contraceptive use increases fast enough to counteract this effect. A number of studies have shown that shorter breast-feeding durations mean shorter intervals between births and thus a larger completed family size (85, 94, 265, 341, 358, 458). Figure 7 shows a number of possible patterns of birth intervals and fertility, including prolonged breast-feeding without contraception, shorter breast-feeding without contraception, and breast-feeding with contraception.

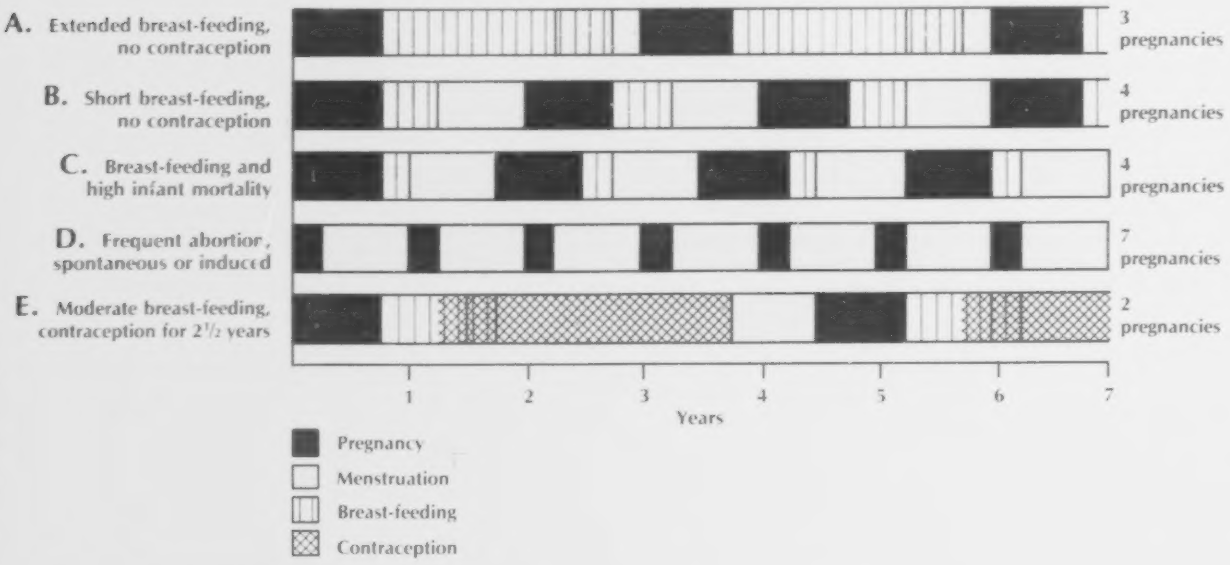
Changing patterns of postpartum abstinence can also make a difference in fertility. The practice of postpartum abstinence in some cultures, mostly in sub-Saharan Africa, adds to the birth interval when it extends longer than postpartum infecundity (338). Abstinence prolonged beyond the return of fecundity often is related to extended breast-feeding. Young, educated, urban women in these cultures seem generally to be breast-feeding less and abstaining for shorter periods, both of which might be expected to increase fertility (76, 132, 163, 247, 249, 338, 349, 388, 406, 419, 491, 499).

In some population groups, especially in urban areas where women are exposed to modernizing influences, fertility may already be increasing, largely because of declines in breast-feeding without compensating increases in the use of contraception (400). Such increases—usually suggested by decreasing birth intervals over time or shorter birth intervals among more "modern" groups—have been observed in Pakistan (95, 426, 505), Senegal (149), South Korea (101), Zaire (86, 477, 488), and among ethnic Indians in Malaysia (112), the !Kung people in Botswana (334, 335, 336), the Yoruba in Nigeria (76, 340, 388, 419), Indians in Canada (478, 495), and elsewhere.

Currently, these fertility increases are the exception rather than the rule. In most areas with available data, increasing contraceptive use has more than compensated for declining breast-feeding, and fertility rates are falling. Increasing contraceptive use and declining fertility are seen in Taiwan, Thailand, and South Korea, for example, where breast-feeding duration has dropped considerably (300, 392). Also, while shorter birth intervals due to shorter breast-feeding have been most notable in urban areas, on the whole urban women have the lowest fertility rates because of more extensive contraceptive use, even though they breast-feed the least (300, 341, 392). Thus, any increases in fertility are thought to be only temporary (16, 417, 477), as was the case in South Korea (101).

Experience in Malaysia illustrates the interaction of breast-feeding and contraception and their differing net effect on birth intervals. Among the Chinese and Malay ethnic groups, women of low parity are breast-feeding less but using contraception more. The result is that birth intervals have changed little. Among Chinese and Malay women of higher parity, increasing contraceptive use is more than compensating for declining breast-feeding, and birth intervals are growing longer. Among the Indian ethnic group, however, women of low parity are breast-feeding less, but few are using contraception. As a result, birth intervals are growing shorter and fertility is rising. An adverse health impact can also be seen: birth weights are dropping and infant mortality is rising (74, 112).

**Figure 7. Patterns of Breast-Feeding and Contraception: Effects on Fertility**



**These bars illustrate different patterns of breast-feeding and contraception and their impact on fertility. Model A depicts a traditional society without contraception, where breast-feeding lasts for two years and postpartum amenorrhea, for 18 months; as a result about three pregnancies occur in seven years. In model B, with much shorter breast-feeding, and model C, with high infant mortality, the interval between pregnancies is shorter and about four pregnancies occur in seven years. Frequent abortion, whether spontaneous or induced, means as many as seven pregnancies in seven years (model D). In model E, where breast-feeding lasts 18 months and contraception begins at 6 months and lasts for 30 months, about two pregnancies would occur in seven years, with an interval of 3½ years between them. Too many pregnancies, closely spaced, can be harmful to maternal and child health.**

### Table 2. Levels of Contraceptive Use Needed to Prevent Increase in Total Marital Fertility Rate if Current Durations of Lactational Amenorrhea Decline to Ten, Six, or Two Months

| Area, Country & WFS Survey Date | Total Marital Fertility Rate | Current Mean Length of Amenorrhea (in Months) | % Currently Using Contraception | Level of Contraceptive Use (in %) Required if Length of Amenorrhea Falls to: | | |
|---|---|---|---|---|---|---|
| | | | | 10 Months | 6 Months | 2 Months |
| **AFRICA** | | | | | | |
| **Kenya 1977–78** | 7.7 | 10.7 | 7 | 10 | 24 | 38 |
| **ASIA & MIDDLE EAST** | | | | | | |
| **Bangladesh 1975–76** | 6.4 | 18.5 | 9 | 32 | 43 | 54 |
| **Indonesia 1976** | 5.3 | 15.7 | 34 | 47 | 56 | 65 |
| **Jordan 1976** | 8.9 | 7.9 | 24 | — | 30 | 43 |
| **Pakistan 1975** | 6.9 | 13.3 | 6 | 17 | 30 | 43 |
| **Sri Lanka 1975** | 5.2 | 14.0 | 35 | 44 | 54 | 63 |
| **LATIN AMERICA** | | | | | | |
| **Colombia 1976** | 5.3 | 7.2 | 37 | — | 41 | 52 |
| **Costa Rica 1976** | 4.0 | 5.3 | 59 | — | — | 66 |
| **Panama 1976** | 4.8 | 6.6 | 46 | — | 48 | 58 |
| **Peru 1977–78** | 6.5 | 9.4 | 29 | — | 39 | 51 |

Source: adapted from Lesthaeghe et al. (341)

Using World Fertility Survey data, Ron Lesthaeghe and colleagues have estimated the increase in contraceptive use that would be needed in various countries to keep fertility from rising if the length of lactational amenorrhea fell to 10, 6, or 2 months (see Table 2). The researchers conclude that in Indonesia and Sri Lanka increases in contraceptive use are likely at least to keep pace with declines in breast-feeding. In Pakistan, Bangladesh, and Kenya, however, "a real contraceptive revolution would be needed" to prevent increases in fertility in the face of declining breast-feeding (341). Estimates such as these are based on models and require many assumptions. Therefore the results are not exact, but rather give a rough idea of the increase in contraceptive use that would be needed to prevent fertility from increasing if the hypothesized declines in breast-feeding were to take place without any other significant changes.

## SUCKLING, NUTRITION, AND FECUNDITY

How does the duration of breast-feeding influence the duration of infecundity? An answer to this question requires an understanding of the physiology of lactation (see box, p. J-543). The hormone prolactin, secreted as a result of an infant's suckling, stimulates the production of breast-milk and also is associated with the inhibition of ovulation (375, 542, 543, 549). A woman's levels of prolactin are highest and the duration of amenorrhea and anovulation is longest when the infant suckles frequently day and night. As suckling frequency decreases, prolactin levels fall, and ovulation resumes.

Only a few studies have tried to examine directly the link between suckling frequency and duration of infecundity. They have found that anovulation is longer with more extensive suckling (315, 376). One study found that the interval between suckling episodes influenced when ovulation resumed, but the average length of each episode and the total time that the infant suckled did not (315). In another study, however, total suckling time, as well as number of suckling episodes, were related to the length of anovulation (376). Animal studies also have shown that the anovulatory period lasts longer with stronger and more frequent suckling (294, 500, 501).

Indirect evidence for the importance of suckling comes from several observations. At the same time postpartum, women who are fully breast-feeding are less likely to be menstruating than women partially breast-feeding. In turn, partially breast-feeding women are less likely to be menstruating than women who are not breast-feeding at all (94, 115, 118, 241, 304, 370, 376, 422). Presumably these differences occur because infants suckle less when receiving food other than breast milk. Similarly, as noted, ovulation, as ascertained in a Chilean study by physiological signs such as basal body temperature and the appearance of vaginal cells, occurred first in women who were not breast-feeding at all, then in women who were partially breast-feeding, and last in women who were fully breast-feeding (433, 434). In addition, in many of the rural and poor populations of developing countries where postpartum amenorrhea lasts longest (51), most infants suckle frequently—as often as 12 to 14 times per day (605). Differences in suckling patterns probably account for some of the variations in return of menses shown in Figures 4, 5, and 6.

While intensive suckling seems to extend postpartum infecundity, it apparently does not do so indefinitely. Even among women who are fully breast-feeding, so that suckling provides their infants' only access to food, fecundity returns gradually with time. In Malaysian and Guatemalan surveys, about 20 percent of fully breast-feeding women were menstruating by 6 months postpartum; about 30 percent were menstruating by 12 months (71). Thus, although full breast-feeding clearly delays the return of fecundity for some time in many women, it is not a guarantee against pregnancy for all.

Several explanations of how nipple stimulation leads to infecundity have been proposed. At the high levels found during lactation, prolactin may act directly on the hypothalamus to prevent the surge of luteinizing hormone (LH), which stimulates ovulation (39, 237), or to change the pulse-like pattern of LH release. Or prolactin may inhibit LH and other sex hormones indirectly, through the activity of dopamine (568). Alternatively, prolactin may act on the ovary, making it unresponsive to LH and other sex hormones (373). This has been demonstrated in vitro but not confirmed. Another possibility is that nipple stimulation, as well as acting through prolactin, prevents ovulation in some way that does not involve prolactin. In a recent study, changes in hormone levels indicating return of fecundity occurred more slowly in monkeys who suckled their infants than in those who did not, even though prolactin production was experimentally suppressed in all the mothers (496).

Substantial evidence links prolactin levels with the extent of suckling. Prolactin levels are highest in fully breast-feeding women and lowest in women who are not breast-feeding (81, 125, 127, 193, 376, 547). They are higher in women whose infants suckle frequently day and night than in women whose infants suckle less often (125, 127, 376). They are higher in fully than in partially breast-feeding women (193, 376, 547). During each suckling episode prolactin levels rise above basal levels. These rises are most marked in the first several months after delivery (124, 548). Over the course of breast-feeding, a gradual decline is seen in both the basal level of prolactin and the rise in response to suckling (122, 125, 127, 133, 193, 238, 376, 544, 546). Presumably this is because infants suckle less as they grow older and begin to receive other food. Nonetheless, milk production can continue when prolactin levels are only slightly above those in nonlactating women (122).

Prolactin levels also are linked to the return of fecundity. Levels are higher for amenorrheic breast-feeding women than for breast-feeding women whose menses have resumed (121, 123, 124, 126, 127, 133, 193, 459). Also, prolactin levels are lower in breast-feeding women with ovulatory first menstrual cycles than in women with anovulatory first cycles (663). This does not necessarily mean, however, that high prolactin levels cause infecundity.

How are suckling, supplementary foods, hormonal levels, and the duration of infecundity all related? Preliminary results from a study in Scotland showed that, as supplementary foods for the infant were introduced, the duration and frequency of suckling declined. Prolactin levels declined along with the decrease in suckling, but more gradually, and ovarian activity resumed gradually. This same pattern occurred whether supplementation started as early as 3 weeks or as late as 24 weeks. None of the 27 breast-feeding women ovulated before supplementation began (376, 648). In this study breast-feeding durations were short. It is not yet known whether the introduction of supplementary foods would always lead to less suckling and thus to resumption of ovulation in other populations with different patterns of breast-feeding and supplementation. Other studies are now underway, examining in detail suckling patterns, infant food supplementation, and hormone levels, to learn more about both the behavioral and the physiological factors that reduce fecundity during breast-feeding and determine when fecundity returns (75, 185, 260).

### Maternal Nutrition and Amenorrhea

A further and important question concerns maternal nutrition. To what extent, if any, does chronic malnutrition lengthen the period of amenorrhea and infecundity in breast-feeding women? Would improved maternal nutrition shorten amenorrhea and thereby increase fertility? Although the impact of maternal food supplementation on the quantity and quality of breast milk remains a matter of dispute (see box, p. J-528), the bulk of evidence indicates that maternal nutrition does not play a major role in determining the length of postpartum amenorrhea.

The hypothesis that nutrition might influence postpartum infecundity was first proposed on the basis of indirect evidence:

- Cross-cultural comparisons showing that postpartum amenorrhea lasts longer in areas where women are generally poorly nourished than where they are well nourished (159).
- Historical and clinical observations showing that improved nutritional status lowers the age at menarche

## THE PHYSIOLOGY OF LACTATION

Breast-feeding depends on four physiological processes, each of which is controlled by a different system of interacting hormones:

- development of milk-producing tissues in the breast,
- initiation of milk production (lactogenesis) after delivery,
- maintenance of milk production (galactopoiesis),
- milk ejection (the "let down," or "draught" reflex) (330, 541, 549, 569).

A mother's ability to secrete milk depends on adequate proliferation of glandular tissue and ducts during pregnancy. This proliferation is stimulated by increases in estrogen, progesterone, and lactogen. Estrogen and progesterone are secreted mainly by the placenta, and lactogen, entirely so. The pituitary hormone prolactin, which activates mammary cells to produce milk after childbirth, is prevented from acting during pregnancy by the high levels of estrogen and progesterone (274, 330, 569).

Following delivery of the placenta, estrogen and progesterone levels decline rapidly, permitting prolactin levels to rise (274, 330, 569). Within 24 to 48 hours, lactation begins. For the first few days, the breast secretes colostrum, a high-protein substance containing many different antibodies. Milk production generally begins by about the second to fifth day, and mature milk is secreted after about two weeks (274, 330, 549, 569). Thereafter, continued milk production depends primarily on suckling (375, 546).

### Prolactin and Oxytocin

Although the hormonal factors in milk production are only partially understood, prolactin is known to be of primary importance. The action of prolactin in milk production appears to be controlled by the presence or absence of a hypothalamic "prolactin inhibiting factor" (PIF). The infant, by suckling, causes the release of prolactin because stimulation of the nerves joining the hypothalamus and breast limits PIF secretion (274, 330, 541, 549, 569).

Milk ejection results from another hormone—oxytocin—released by the pituitary in response to suckling. Oxytocin, which also causes uterine contractions for several days after delivery, causes cells surrounding the alveoli, where the milk has collected, to contract, forcing milk into ducts and sinuses under the areola. The "let down" occurs when contracting cells and muscles within the breast force out milk that has already been secreted. A nursing mother experiences "let down" as a physical sensation in her breast within about 30 seconds to a minute after the infant starts to suckle. Contrary to popular opinion, therefore, "let down" is not caused by negative pressure created by the infant's suckling nor by rapidly increasing milk secretion, but by a neurogenic reflex which stimulates oxytocin release (274, 330, 569).

(158, 159, 162) and that starvation leads to amenorrhea (162, 522).

To conclude from these observations, however, that differences in maternal nutrition explain differences in the length of postpartum amenorrhea is not warranted (54). Other differences between cultures—particularly differences in breast-feeding patterns—can account for differences in length of amenorrhea. The Hutterites of North America are sometimes cited as an example of a well-nourished, noncontracepting population whose infants are breast-fed but where postpartum amenorrhea is brief (507). The reason for this short period of amenorrhea may not be nutritional, however, but rather infrequent suckling and early infant food supplementation (252). By contrast, a study of presumably well-nourished US women who breast-fed at frequent intervals found that postpartum amenorrhea lasted more than 12 months (304). Similarly, links between nutritional status and age at menarche or between starvation and amenorrhea cannot necessarily be extrapolated to postpartum women because different physiological processes are involved (86, 161, 522).

The best direct evidence for a strong effect of maternal nutrition on the length of amenorrhea comes from a study in the Gambia. In this study changes in both prolactin levels and length of postpartum amenorrhea were linked with changes in nutrition. Prolactin levels in breast-feeding women were higher during the rainy season, when their caloric intake is particularly low. Also, substantial supplementation of mothers' diets lowered prolactin levels (347). Lactational amenorrhea, as evidenced by estrogen levels, lasted about 10 months in the women who received food supplements compared with about 16 months in women, studied earlier, who received no supplements. As a result, average birth intervals were shorter for the women receiving supplements (348). The researchers speculate that prolactin increases in response to poor nutrition in order to maintain milk production, even if at the expense of maternal nutritional status (347). Alternatively, limited milk production in the poorly nourished women (583) might lead to more intense suckling by the infant and therefore higher prolactin levels and longer amenorrhea (641). The number of suckling episodes, already at 10 to 16 a day, did not change with supplementation (347), but detailed analysis of suckling patterns has not been reported. Another possibility is that prolactin levels rose due to stress caused by malnutrition (545) or by particularly hard work during the rainy season.

By contrast, a number of other studies have found that diet or nutritional status made little difference to the length of postpartum amenorrhea. Bangladeshi studies by Sandra Huffman and others found no relationship between maternal nutritional status and amenorrhea (100, 241, 244, 245). In a Guatemalan study, better maternal nutritional status during lactation (assessed by weight and other body measurements) and better diet (assessed by caloric intake during pregnancy and lactation) had a small, sometimes statistically significant effect in reducing the length of amenorrhea. Duration of breast-feeding, however, was a far more important factor (115–118). The infants' caloric intake in supplementary foods also had more effect on amenorrhea duration than did maternal nutrition, perhaps because of decreased suckling with increased supplementation (118). A Mexican study reached similar conclusions. Amenorrhea was shorter among mothers receiving food supplements (92), but the infants suckled less, in part because they were given supplements as soon as their growth rates or their mothers' milk production faltered (91, 93). In general, it is now thought that postpartum amenorrhea (and infecundity) may last only a few months longer in women of the poorest nutritional status than in women with the best nutritional status within a community (54, 641).

Likewise, studies have not found that a woman must be at a minimum weight or a minimum weight-for-height before her menses resume postpartum (87, 118, 241, 244, 509), as may be necessary for menarche (158, 159, 162). In fact, a Guatemalan study found that women lost weight during lactation and were losing weight even as menses resumed (118).

## HORMONAL CONTRACEPTION WHILE BREAST-FEEDING

In assessing the impact of contraception on breast-feeding, research has focused primarily on hormonal contraception. Basic concerns are: do estrogens and/or progestins have any effect on the quantity or content of breast milk, and, if so, how much? Will the infant be affected? Despite more than 50 studies, the available evidence is inconclusive. The following observations can be made:

- The difficulties of measuring lactation and identifying effects of hormones make all conclusions tentative, as a number of review articles have pointed out (66, 99, 248, 326, 428, 441, 535).
- Combined estrogen-progestin oral contraceptives decrease milk volume in some cases, but pills with 0.05 mg or less of estrogen do not appear to affect infant growth.
- Progestin-only contraceptives, whether pills or injectables, either have no measurable effect on milk volume or may increase it.
- The small doses of hormones used for contraception do not appear to prevent initiation of lactation. Limited research suggests but does not prove that, when hormonal contraceptives—combined or progestin-only—are started early, milk production may not be as great as when they are started later.
- Minute amounts of hormones are transmitted to the infant in breast milk. No serious immediate effects have been observed, but long-term effects are unknown.

### Research Problems

There are at least three major problems in assessing the impact of hormonal contraceptives on breast-feeding (248):

1. What aspects of breast-feeding should be measured—duration of lactation, perceived need for supplementary feeding, amount of milk obtained by breast pump, immediate or long-term infant weight gain, or composition of milk, including nutrients and hormones?
2. What standard of comparison or control group should be used?
3. To what extent do the different hormones used in various formulations have different effects?

An optimal measurement of breast-feeding and the content of breast milk would involve weighing and analyzing the composition of the milk that an infant consumes. Of course this cannot be done directly; instead, indirect measurements must be used. As a result, some studies simply ask women for their impressions. Others record the proportion of women wanting to breast-feed who are able to do so, the age of the child at initial supplementation, or the duration of breast-feeding. All these indicators, however, are influenced by personal and environmental factors that can be difficult to identify. Some studies have tried to measure the quantity of milk by weighing the child before and after a feeding, but any fluid loss must also be measured. Some researchers have looked for possible changes in the nutritional value or hormone content of breast milk, but it is not certain whether the milk samples used are representative of the milk that infants obtain (274, 521). Furthermore, the composition of an individual woman's milk fluctuates considerably (248).

Because of the wide range of values that is considered normal, a meaningful assessment requires a comparison or control group. Some studies compare the current and past experience of the same women, even though a woman's age and other circumstances change, and her memory may be inaccurate. Other studies compare users of hormonal contraceptives with women using either other methods of contraception or none. But women who choose hormonal contraceptives may differ from other women in ways that affect breast-feeding, and it is seldom possible or ethical to assign women randomly to different methods or to placebos. Finally, both women and health personnel may have expectations or attitudes that influence their assessments unless the study can be conducted on a double-blind basis (441).

A third problem is the great variety of hormonal formulations now available. There are two estrogens and at least a dozen progestins that have been used together in different combinations and amounts in combined oral contraceptives, as well as half a dozen progestins used alone. Each of these preparations should be evaluated separately because the steroids may act and interact differently.

To emphasize the best evidence available, this review (including Tables 3 through 6, pp. J-558–563) focuses on clinical studies in which control groups were used and the number of women studied was relatively large—20 or more. As a result, several often quoted studies are not included (63, 98, 290, 345, 429, 464, 472, 539, 636, 656, 682). Even when larger, controlled studies are examined, conclusions are tentative at best.

### Breast Milk Quantity and Duration of Breast-Feeding

Most but not all studies of combined estrogen-progestin contraceptives report some adverse effect on breast-feeding performance (see Tables 3 and 4, pp. J-558–560). By contrast, nearly all studies of progestin-only contraceptives have found either a beneficial effect or no effect (see Tables 5 and 6, pp. J-560–563).

**Number of Groups of Breast-Feeding Women Using Different Hormonal Contraceptives, by Result**

| | Some Adverse Effect | Positive or No Effect |
|---|---|---|
| **Combined OCs** | 21 | 7 |
| **Progestin-only** | 1 | 34 |

(Studies are summarized in Tables 3–6, pp. J-558–563. Studies with fewer than 20 women in a group or with no comparison group or no formulation specified are omitted. Each study report may include several groups using different formulations or starting the same formulation at different times.)

Six studies have directly compared combined orals and progestin-only contraceptives. Four found a reduced volume of breast milk, more infant supplementation, or a shorter duration of breast-feeding with combined estrogen-progestin pills and a neutral or positive effect with progestin-only formulations (174, 198, 240, 291). A fifth found shorter breast-feeding with three of four combined orals and longer breast-feeding with all three progestin-only formulations studied (195). The remaining study found no adverse effects for either type (454).

To minimize the impact of the many factors other than hormonal contraception that may influence breast-feeding, some studies have assigned contraceptives to women randomly on a double-blind basis, giving placebos to control groups (288, 291, 381, 502, 538). Among these studies, three of the four involving combined oral contraceptives found some adverse impact, including need for more infant supplementation (288, 291, 381); a fourth found no reduced milk yield (502). One involving estrogen alone found no impact on the initiation of lactation (538). Both of the double-blind studies on progestin-only contraceptives found a neutral or positive effect (291, 538).

The magnitude of the effects of hormonal contraceptives is uncertain. These studies report average results, and many women were not affected at all. Furthermore, studies which looked at more than one measure of breast-feeding performance sometimes found conflicting results (79, 240, 288, 291, 504).

Because the ultimate question is whether the infant is receiving enough breast milk, the most important measure may be infant weight gain (248, 291, 391). When considering weight gain, however, supplementary feeding must be taken into account (see box, p. J-530). Only two studies report the weight gain of infants receiving only breast milk. One found that a combined oral contraceptive made no difference to weight gain (79). The other found a beneficial effect with two progestin-only injectables—depot medroxyprogesterone acetate (DMPA) and norethisterone enanthate (NET EN) (298). Of the seven studies with combined orals that evaluated infant weight, the three that found significantly less weight gain used compounds with estrogen levels above 0.05 mg (ME 0.08–0.10) (313, 316, 381). The four that found no significant difference in weight gain (79, 288, 291) or caloric content of milk (240) involved lower estrogen doses. Two of these four used Norinyl 1 + 50 (with ME 0.05 mg), which is widely distributed by the US Agency for International Development (240, 281). Even when differences are seen, they may lack importance if weight gain remains in the normal range.

To some extent, differences in impact may depend on when contraception begins. Very little research has addressed this issue, however. Of three reports on women taking combined orals or estrogens alone (288, 502, 538), all but one short study (288) indicated no adverse effect on the initiation of lactation. With progestins, when users were compared with controls, none of nine major studies found any adverse effects on initiation of lactation or on early milk production when the progestins were started in the first week postpartum (17, 88, 195, 298, 313, 487, 504, 538, 631).

Studies that started the same hormonal contraceptive at various times reach a somewhat different conclusion. They have found that milk production or breast-feeding duration was generally less in the women who began use earlier. This pattern was seen in all three such studies of combined oral contraceptives (254, 381, 502) (see Tables 3 and 4, pp. J-558–560). Similarly, in two studies the beneficial effect of progestin-only contraceptives was less marked with earlier administration (195, 622), but in two it was not less (298, 504) (see Table 5, pp. J-560–562).

Another consideration is the doses of the estrogens and progestins and their independent and combined effects. Two studies have found less milk production at higher doses of progestins in combined pills (164, 291). In one of these studies the pills with higher progestin doses generally had higher estrogen doses, too (164). Two other studies, however—one of progestins at two doses (195) and the other of estrogens at two doses (454)—found no difference between the doses in these combined OCs. No research has been reported on the relative effects of different doses of progestin-only contraceptives.

The estrogen component of combined pills has generally been blamed for adverse effects. Estrogen doses have dropped over the years, but studies of combined pills with 0.05 mg mestranol (ME) or ethinyl estradiol (EE), the most commonly used doses today, still report reduced milk yield and/or breastfeeding duration. With an even lower estrogen dose (0.03 mg EE), however, two recent studies could find no differences in infant weight gain, duration of breast-feeding, or duration of full breast-feeding in one case (79) or in duration of breastfeeding in the other (454) (see Table 3, p. J-558). Preliminary data from a WHO study of combined pills (0.03 mg EE) show 35 percent less milk volume after six weeks than in controls but no difference in infant weight gain (611).

Estrogens were assumed responsible for adverse effects of oral contraceptives on lactation because large doses of estrogens have been widely used to suppress lactation in women who did not want to breast-feed. Several studies of various estrogen doses compared with placebos, however, have shown that even at very large doses—much higher than those used for contraception—estrogens are not very effective at suppressing lactation (218, 290, 310, 574). Whether a woman wants to breast-feed and, above all, how much the infant is allowed to suckle now seem to be more important to the initiation of lactation than estrogen intake. This is illustrated by two double-blind studies comparing the same hormonal contraceptive (lynestrenol 2.5 mg + ME 0.075 mg) to a placebo. In one study the women did not breast-feed their infants, and the oral contraceptive and the placebo, administered for the purpose of suppressing lactation, did so with equal effectiveness (62). In the other study, in which the women were breast-feeding their infants and were taking the pills for contraception, lactation was not inhibited (502, 503).

The relative effects of the various progestins are even more complex (130, 142, 186, 286). Progestins of the same weight may differ in progestational potency, so that doses cannot readily be compared. Progestins also vary in their inherent estrogenic, antiestrogenic, and androgenic effects, which may influence their impact on breast-feeding. Further, when a progestin is combined with an estrogen, the effect differs from that of either compound separately. Whether the progestin is given orally, by injection, or by implant also may make a difference.

There are two main groups of synthetic progestins—those derived from 19-nortestosterone (which include norgestrel, norethindrone, norethynodrel, lynestrenol, and norethindrone enanthate) and progestins derived from 17α-hydroxyprogesterone (which include depot medroxyprogesterone acetate (DMPA), megestrol acetate, chlormadinone acetate, and quingestanol acetate). Although there are physiologic reasons that 19-nor derivatives might be more likely to inhibit lactation than 17α-hydroxy derivatives (413, 531), this does not appear in fact to be the case. Among 19 studies of progestins involving 35 groups of women, an inhibiting effect was found in only one (223). This was a study of chlormadinone acetate, no longer widely used, which in four other studies had a neutral or beneficial effect (88, 175, 195, 631) (see Tables 5 and 6, pp. J-560–563).

Progestin-only contraceptives may increase the level of prolactin, which would be expected to promote milk secretion. In one small study prolactin levels rose higher during suckling among DMPA users than among women using nonhormonal contraception (90).

### Breast Milk Composition

Hormonal contraceptives have little effect on the composition of breast milk. Most of the studies on milk composition, conducted since the late 1960s mainly in Egypt, India, and Bangladesh, report no significant differences in the concentrations of protein, fat, or lactose between the breast milk of women using hormonal contraceptives and that of nonusers. With combined pills, some studies have found higher concentrations of protein or fat, while others have found lower concentrations, sometimes even with the same compound (see Table 7, p. J-563). With progestin-only contraceptives, the concentrations of protein and fat were generally either increased or unchanged (see Table 8, pp. J-564–565). The lactose concentration was not affected by either type of hormonal contraceptive. In Bangladesh, with combined pills, Douglas Huber and colleagues found that higher fat content compensated in caloric value for a lower volume of milk. Thus the total caloric content of 24-hour milk samples was not significantly different for combined pills, a progestin-only injectable (DMPA), and controls (240). By contrast, with two progestin-only injectables (including DMPA), several researchers working in Egypt found that fat content was lower and milk production was increased, but not enough to make up the deficit (223, 631).

In the only report on the impact of hormonal contraceptives on the immunologic protection conferred by breast milk, there were no significant differences in immunoglobulin concentration between breast milk of women using DMPA or NET EN and those who were not (145).

### Hormones in Breast Milk

Small amounts of steroids from hormonal contraceptives appear in breast milk, are consumed by the infant, and can be detected in the infant's blood plasma. Reported short-term effects appear to be rare and minor. The chances of any long-term effects have not been studied, but the adverse effects on the fetus of hormones administered in early pregnancy have raised concerns about steroid transmission in breast milk.

The most comprehensive investigation of hormones in breast milk has been conducted by Staffan Nilsson and colleagues in Uppsala, Sweden (411, 412, 413, 414) (see Table 9, p. J-565). They measured the levels of progestin and estrogen compounds in both maternal blood plasma and breast milk. For all hormones measured, the dose received by the infant was far less than one percent of the maternal dose, a finding similar to those of other studies—both early studies of radioactively labeled steroids (328, 329, 398, 438, 560, 592) and other, more recent studies using radioimmunoassays (311, 494, 533). The progestins differ in how much of the maternal dose appears in the breast milk, however. With megestrol acetate, a 17α-hydroxy derivative, the ratio of steroid concentration in maternal plasma compared with the concentration in milk was 100:80 (413). With norgestrel, a 19-nor derivative, the ratio was much lower—100:15. Nilsson and colleagues studied various doses of norgestrel. At the dose used in progestin-only contraceptives, the concentration of the hormone in milk was too low to be detected. At higher doses, such as those used in combined OCs, the hormone could be found in breast milk and in the infants' blood plasma. The concentration in the infants' blood was similar to what would be seen in women who had taken an equivalent oral dose of norgestrel; this indicates that the infant metabolizes and excretes the hormone at about the same rate as the mother (411).

Other studies also have found that the proportion of the progestin appearing in breast milk is greater for 17α-hydroxy derivatives than for 19-nor derivatives, whether given as pills, implants, or injections (311, 494, 533, 540). With contraceptives taken orally each day, the quantity of steroids received by the infant remains the same from day to day. Because an injection at first produces relatively high serum concentrations of contraceptive hormone, the daily dose to the infant is also relatively high at first and then declines. This high initial dose might be of particular concern if an injection were administered immediately postpartum, when the infant's ability to metabolize and excrete the drug is most immature (216, 465). With one of the new implants, which gradually release a controlled dose, norgestrel was not detectable in milk after the first day and norethindrone, not after the first week (540).

Estrogens appear to be transferred to the infant less than the 17α-hydroxy progestins but more than the 19-nor progestins. EE, for example, has a moderately low plasma-to-milk concentration ratio—100:25. Very low absolute amounts appear in breast milk, and the infant receives a very small proportion of the daily maternal dose (412) (see Table 9, pp. J-565–566). At the doses used for contraception, Nilsson and colleagues could not detect EE in milk (412). The endogenous estrogen estradiol also has been evaluated, both because it is naturally present in the blood plasma of adult women and because it is a potential contraceptive (26, 414, 609). Its plasma-to-milk concentration ratio is less than 100:10, and the absolute amount passed into the milk is extremely small (414).

In studies of hormone levels at specified intervals after administration of combined or progestin-only pills, levels in both plasma and milk were highest at 2 or 3 hours and dropped thereafter (408, 411–413, 494, 540). Thus women taking orals could minimize hormone reaching the infant by taking pills either just before or after a feeding and when the time to the next feeding would be longest—perhaps the last evening feeding or, if a mother leaves her infant to go to work all day, the morning feeding (48).

The difference between progestins in the proportion of the maternal dose transferred to breast milk may be at least partially due to the differing capacities of progestins to bind with serum hormone binding globulin (SHBG) in the mother's blood. Only the portion that is not bound to SHBG can pass into the milk (411–415, 565, 566). High SHBG levels in the immediate postpartum period may mean that more of the hormone will be bound and less passed into the milk during this period (415, 484). The lower fat content of colostrum compared with mature milk (330, 630) also suggests that steroid transfer may be relatively low during the first few days after delivery. Contraceptive steroids are fat-soluble and thus are found in higher concentrations in the high-fat milk obtained at the end of a feeding than in the low-fat milk obtained at the beginning of a feeding (411, 413).

The critical question, which remains unanswered, is what effect these small amounts of hormones may have on the infant. No link between hormones consumed by breast-fed infants and subsequent diseases or developmental disorders has been established, but potential long-term effects have not been thoroughly studied. As for short-term effects, there have been case reports of transient breast enlargement among infant sons of women taking combined oral contraceptives (110, 356, 412). This may be due to the estrogen component of the pills. Neonatal breast enlargement attributable to natural maternal estrogens occurs commonly and subsides spontaneously, however (42, 110). Several studies that have looked for possible effects on infants have not found any (98, 298, 299, 381, 506).

The reason for concern about infants receiving hormones is that naturally produced hormones are known to influence normal physical development at various points. Furthermore, early in pregnancy, fetal exposure to administered hormones or abnormally produced natural hormones (such as those produced by a tumor) can lead to birth defects (594) or, in the well-known instance of the estrogen diethyl stilbestrol (DES), vaginal cancer when a daughter exposed in utero reaches adolescence (228). In late pregnancy, however, levels of natural estrogens and progesterone are high, without adverse effect on the fetus or on subsequent development. Male infants may be especially susceptible from one to three months when testosterone levels rise and then fall (154). Thus the time of administration may be crucial, but more study is needed.

Animal studies, although not necessarily applicable to humans, are useful for studying long-term effects because animals have shorter life spans. Three studies have found adverse effects on the rate of sexual maturation or on subsequent fertility in rats whose mothers received certain progestins during lactation, generally at doses higher than those used by women for contraception (10, 179, 493). A fourth study found no effect in rats at five times the equivalent human dose (570).

Several other issues have been raised about the use of hormonal contraceptives during breast-feeding, but little clear evidence is available to resolve them:

- In the immediate postpartum period women are at higher than usual risk of thromboembolic disease (310, 570). Since, to varying degrees, oral contraceptives increase the risk of thromboembolic disease (474), women who use them in the immediate postpartum period might be at particularly high risk.
- One study found that nursing infants of OC users had higher rates of neonatal jaundice than other infants (602), but other studies found no such association (40, 180, 368).
- Several reports suggest that amenorrheic breast-feeding women who take the pill resume menstruating sooner (394, 454) and, if they stop the pill, become pregnant sooner (50) than women who have taken no pills. Other studies and comments raise some doubts, however (239, 436). Menses-like withdrawal bleeding after a cycle of pills does not indicate ovulation, return of which depends primarily on suckling patterns.

In summary, research to date suggests that combined orals at certain doses reduce the volume of breast milk in some women, while progestin-only contraceptives—whether oral, implant, or injectable—may have no effect or may increase milk volume. In any case, the effects of hormones used in low doses on milk quantity and composition do not appear to be great, although the possibility of long-term effects on infants from transmitted steroids has been neither confirmed nor dismissed. Overall, observed effects of combined orals do not seem to be large enough to rule out these contraceptives for breast-feeding women who want to use them (see p. J-554).

## ENCOURAGING BREAST-FEEDING

The challenge for family planning programs, either as separate programs or as part of integrated primary health care, is

- to preserve breast-feeding where it is now common and to encourage and facilitate breast-feeding where the practice is declining, as well as
- to provide safe and effective means of contraception to breast-feeding women at the appropriate time to prevent unwanted pregnancies.

Breast-feeding should be promoted for reasons related directly to infant nutrition and health, not primarily for contraception. The contraceptive protection provided by breast-feeding is too uncertain for individual women when modern family planning methods are available as an alternative. Thus two strategies are necessary. Where prolonged breast-feeding is common, women should be encouraged to continue breast-feeding and to use contraception to prevent another pregnancy that would interrupt breast-feeding. Where breast-feeding is now declining, women should be encouraged for the health of the infant to breast-feed as long as feasible and to start effective contraception before lactational infecundity ends.

### National Programs to Encourage Breast-Feeding

In the past decade over 15 countries have adopted policies or programs to encourage breast-feeding, for both health and economic reasons (35, 274). The policies have been of two types: (1) demand policies, which attempt to increase women's motivation to breast-feed by educating women and health professionals and by changing hospital and employment practices to facilitate breast-feeding; demand policies also would deter bottle-feeding by limiting advertising of infant formula; and (2) supply policies, which make bottle-feeding more difficult by restricting the availability and supply of infant formula, bottles, and nipples (35). Most of the national progams are in the early stages of development, and their effectiveness cannot be fully gauged.

Many developing countries have instituted educational, or demand-oriented programs. They include Brazil, Colombia, Indonesia, Jamaica, Malaysia, Mexico, Thailand, and Trinidad and Tobago (1, 14, 35, 492, 525, 629, 644, 676). Some have placed limits on the advertising practices of companies that market infant formula. In at least four countries—Argentina, Malaysia, Singapore, and Papua New Guinea—women's groups provide support and encouragement for breast-feeding by visiting new mothers in hospital wards and at home (274, 319, 532). Another way to encourage breast-feeding is to make it easier for working women. Many nations encourage nursing breaks, permit shorter working hours, call for creches (nurseries) in places of employment, and in other ways attempt to facilitate nursing (279, 473, 605). In Nicaragua a broad effort to promote breast-feeding has been proposed, including

- prenatal education,
- supplementary food programs for lactating women,
- mass-media advertising,
- breast-feeding education in schools and universities,
- mandatory maternity leave before and after childbirth,
- creches at work places, with lactating women granted a free hour daily to breast-feed, and
- legislation to control marketing and promotion of breast milk substitutes (35).

A small number of countries have instituted supply-type policies. Ghana and Jamaica have restricted the import of infant formula, and in Guinea-Bisseau and Papua New Guinea formula, bottles, and nipples can be sold only in pharmacies on a doctor's prescription. Algeria has nationalized the import of all infant formula, thus eliminating advertising and promotional efforts of infant formula manufacturers (35).

The frequently cited program of Papua New Guinea, which operates mainly in the capital city of Port Moresby, combines demand and supply policies. Demand policies were started in 1975. Health workers began to promote breast-feeding. Hospital staffs and local women's groups taught women breast-feeding techniques. Manufacturers were forbidden to distribute formulas in hospitals, and all advertising of formula on the radio was banned. By 1977 it was clear that these measures were not increasing the rate of breast-feeding, and legislation was passed making bottles, nipples, and formula available by prescription only. Before issuing a prescription, a health worker is required to instruct the woman in the proper preparation and storage of formula (18, 319). The program has not been fully evaluated. Small surveys suggest an increase in breast-feeding in Port Moresby, from 65 percent to 88 percent of children under 2 years old at the time of survey (18, 319).

In May 1981 the World Health Assembly approved an International Code of Marketing encouraging countries to restrict advertising, distribution of free samples, and other promotion of infant formula and to ensure proper labeling (608). The US government, although it provides support for a number of breast-feeding programs (263, 264, 555), opposed the code on the grounds that it recommended a complete ban on advertising infant formula to the general public, which runs counter to US constitutional guarantees of free speech (556).

Many observers believe that easy access to breast milk substitutes and exposure to misleading advertisements by in-

مخزن الشعب للادوية
لصاحبها يحيى نعمان فيروز

**Breast-feeding is declining in urban areas of many developing countries. How much effect do urbanization, jobs outside the home, and other modern influences have? Or does the promotion of infant formula, prominently displayed here by a shopkeeper in the Yemen Arab Republic, discourage breast-feeding?** (Stina Almroth) fant formula manufacturers encourage the use of formula by families who do not recognize the full implications of stopping breast-feeding (32, 151, 189, 274, 447). On the other hand, programs restricting the availability of infant formula are controversial because they limit individual choice (6, 437). Edward Baer, Associate Director of the Infant Formula Program of the Interfaith Center on Corporate Responsibility, notes that:

> The task facing national governments . . . is to find ways to make breast milk substitutes available to those who really need them, without implicitly or explicitly promoting their use for the whole population. (35)

### Role of Health and Family Planning Personnel

While governments may consider a wide range of policies to promote breast-feeding or to discourage bottle-feeding, family planning and maternal and child health programs can play a very practical and positive role in encouraging breast-feeding by

- providing information and support for breast-feeding to women and their families from the beginning of pregnancy,
- helping to solve breast-feeding problems,
- changing hospital and clinic routines to help establish lactation and to eliminate artificial feeding from maternity wards, except when indicated for strictly medical reasons.

These measures can increase both a woman's motivation to breast-feed and her ability to do so successfully.

Family planning and other health workers should know about breast-feeding techniques so that they can teach the "art of breast-feeding" to women. Several surveys have shown, however, that health professionals are often misinformed about breast-feeding (68, 211, 342). All health workers should be taught that frequent suckling—the pattern of breast-feeding in many traditional societies—is necessary to maintain a high level of milk production. Frequent suckling is especially critical in the first weeks after childbirth, when lactation is being established. If there are long intervals between feedings or rigid schedules, the reduced suckling causes shortages of milk. A woman may then have to supplement breast-feeding or turn entirely to bottle-feeding. Early supplementation with cow's milk or other foods further limits the production of breast milk since an infant who is not hungry may be less inclined to suckle. Traditional practices such as delaying breast-feeding for two to four days after birth or nursing with only one breast may also reduce the milk supply (5).

Frequent feeding also may alleviate some of the common problems of breast-feeding—sore and cracked nipples, breast engorgement, and breast infections—which sometimes unnecessarily curtail breast-feeding (604). In an early study of over 100 women, those feeding on a rigid 4-hour schedule had more nipple soreness and breast engorgement than women feeding their infants "on demand" (255). Also, infrequent feedings can cause milk to pool in the breast and lead to inflammatory mastitis (270).

Family planning workers can assure women that nipple soreness usually stops within several weeks after delivery. Exposing the breasts to the air or to dry heat helps dry and toughen nipples. If only one nipple is affected, women should breast-feed the baby on the opposite breast first in order to permit the milk to let down, thus reducing the suckling pressure on the sore nipple (330, 604). Continued breast-feeding is also recommended if a woman develops mastitis. Breast-feeding women should be alert to the symptoms of mastitis—redness and pain in one or both breasts—and should be advised to obtain medical treatment as soon as possible (330).

In addition to information about breast-feeding techniques, women also need confidence that they can breast-feed successfully. Lack of confidence as well as stress and anxiety may interfere with the milk ejection (or "let down") reflex, which makes the milk accessible to the infant (272, 330). If the breast milk does not let down, the mother may believe her supply is inadequate and turn to bottle-feeding. In traditional societies other women—sometimes called doulas (272, 468)—provide support and encouragement to new mothers. The absence of this support in modernized societies may impair a woman's ability to breast-feed (468). In these societies support can come at least partly from health workers instead. A woman's confidence in her ability to breast-feed may also be increased if she keeps a growth chart for her child and, when the child is weighed during clinic visits, records the child's weight gain (391, 607). The growth chart also alerts health workers to child health problems (191, 391). (See photo, p. J-552.)

Information and support for breast-feeding should begin early in pregnancy. In modern medicine, care for all aspects of breast-feeding has fallen to the pediatrician (600). Yet many women choose during pregnancy which method of feeding to use (138, 285). Thus, obstetricians and midwives are often in the best position to encourage women to begin breast-feeding.

### Changing Hospital and Clinic Routines

Physicians, midwives, and other health workers can actively encourage breast-feeding not only by providing information to their clients but also by altering hospital and health center policies that discourage breast-feeding. Since many women in urban areas deliver in hospitals, these policies have wide impact. Studies in Thailand and Malaysia found that women who had delivered in medical facilities were less likely to breast-feed than women who delivered at home even after taking into account the influence of socioeconomic status (73, 307). This suggests that hospitals may have discouraged breast-feeding, and could be one reason that urban women breast-feed less.

Hospitals in both developed and developing countries discourage breast-feeding by separating the mother and infant immediately after childbirth, administering lactation suppressants, offering unnecessary supplementary bottle feedings, establishing inflexible feeding schedules, and, during labor, performing episiotomies routinely, causing the mother pain which may interfere with "let down," and administering certain drugs such as barbituates, which may impair a newborn infant's ability to suckle (64, 250, 600, 605, 610). In some hospitals in Costa Rica, Guatemala, and Zaire, for example, women are separated from their infants for 12 to 24 hours or for the entire hospital stay, thus preventing early initiation of breast-feeding (365, 517, 605). A Jamaican study found that supplementary bottle-feeding in the hospital—often routinely given without medical indications—increased the likelihood of early weaning. Only 5 percent of the women whose infants were supplemented returned to full breast-feeding at home (181).

Changing these hospital policies can facilitate breast-feeding (365, 517, 600). In two of three Guatemalan hospitals the mean duration of breast-feeding was significantly greater among women who were allowed to breast-feed their infants immediately after delivery than among women who did not see their infants for 12 hours (517).

Restricting the availability and promotion of infant formula in hospitals also may encourage breast-feeding. In some countries representatives of infant formula manufacturers have visited hospitals and given free samples of formula to newly delivered mothers (605, 664). Representatives often wore nursing uniforms (188, 189). In addition, maternal and child health centers and maternity wards have displayed posters advertising infant formula. Eliminating these practices should help avoid giving mothers the impression that health workers favor bottle-feedings.

Family planning clinics and staff also may play a role in encouraging breast-feeding. In Malaysia women who lived nearest to (and presumably attended) integrated maternal and child health care clinics were significantly more likely to start breast-feeding and to breast-feed longer than women who lived near family planning clinics on tea plantations. While other factors may be responsible, it is possible that the staffs of the tea plantation clinics discouraged breast-feeding or simply failed to discuss it at all (73).

Women who have to combine breast-feeding with jobs or other activities outside the home should be encouraged to try mixed feedings, either using prepared formula or expressing milk from the breasts by hand or with a manual pump, instead of giving up breast-feeding altogether. Women who are definitely planning not to breast-feed should be given full and careful instructions on how to prepare, store, and administer other food safely.

Overall, since women are moving into urban areas, taking paying jobs, and discovering alternatives which they may prefer to traditional ways, breast-feeding is unlikely ever to be as universal and prolonged as in the past (452). Yet the experience of developed countries suggests that trends in breast-feeding have been strongly influenced by changing biomedical knowledge. During the 1940s, 50s, and 60s, while breast-feeding was declining, medical textbooks and scientific literature offered little justification for preferring breast to bottle (70). As William Butz notes, "The scientific evidence that breast-feeding provides a superior infant food and a natural contraceptive was only established in the late 1960s" (70). As that evidence has been disseminated among both health personnel and the general public, the percentage of women breast-feeding has increased, beginning with the most educated groups. In developing countries today, however, perhaps because of a lag in dissemination of this knowledge, breast-feeding is practiced least by educated urban women. It is possible that in developing countries also, as health professionals and individual women become better informed about the proven health benefits of breast-feeding, more of them will encourage and support this traditional practice, but for well-established scientific reasons.

**In some hospitals newborn infants are separated from their mothers and given water and other fluids by bottle—which may make breast-feeding more difficult when the mother and child return home.**

## CONTRACEPTION DURING BREAST-FEEDING

Providing safe and effective methods of family planning for breast-feeding women is an important concern for family planning programs. Breast-feeding women constitute a substantial percentage of ever-married women of reproductive age in many developing countries (see Figure 8). After the first few months of breast-feeding, these women run an increasing risk of becoming pregnant, and they have a particularly strong reason to avoid immediate pregnancy.

In determining which contraceptive methods should be provided to breast-feeding women and when, family planning workers need to consider at least four different factors. These are:

1. the personal preference of the woman,
2. the availability and convenience of different methods or procedures at different times, which often has a great impact on choice of contraceptive,
3. the impact on fertility of starting different methods at different times after delivery, which, like other considerations, varies greatly depending on personal and community circumstances, and
4. the possible effects on lactation, which so far have been studied mainly with respect to hormonal contraceptives.

Theoretically, each of these four factors—personal preference, availability, fertility impact, and effects on lactation—should be taken into account in choosing a family planning method and deciding when to start it. There are eight major family planning methods—combined oral contraceptives, progestin-only contraceptives, IUDs, male or female sterilization, barrier methods, coitus interruptus, and periodic abstinence—and there are at least five different times when a method can be started—immediately postpartum, after a postpartum check-up, when food supplementation starts, when menses resume, or at some specific date, such as 6, 12, or 18 months postpartum.

In practice, these many possibilities tend to be reduced to three questions:

- What methods can be initiated immediately postpartum or at an early postpartum check-up?
- How long can a breast-feeding woman delay the use of contraception and still be reasonably sure of avoiding another pregnancy?
- When can hormonal contraceptives of various types be introduced without the risk of seriously affecting lactation?

### Postpartum Services

Programmatic availability and personal convenience will always be important factors in the choice and use of contraceptives, especially when evidence of adverse effects is inconclusive. Thus a great deal of attention has focused on the provision of family planning services immediately after delivery. This is most appropriate for women who deliver in a hospital or health center and so are in close touch with health personnel at that time. Although fully breast-feeding women are infecund for a minimum of several months after delivery, the overlap in contraceptive protection with methods started immediately postpartum should be weighed against the possibility that women may not return later for a postpartum visit or for family planning services. Furthermore, even though some women may not wish to begin contraception immediately, family planning education at the time of delivery may lead to greater acceptance of family planning services later (683).

Combined oral contraceptives are not a recommended method for use immediately after delivery. Recognizing that these contraceptives may have an adverse effect on lactation, a number of organizations, including the International Planned Parenthood Federation (IPPF) Central Medical Committee (262), the WHO Expert Committee on Maternal and Child Health (610), and the American Public Health Association (21, 22), suggest that preference be given to other methods, especially while the infant is very young. IPPF, for example, advises that "combined oral contraceptives should not be started until lactation is well-established" (262). The American Public Health Association recommends "other family planning methods, especially when human milk is the infant's only source of nutrients" (21). Furthermore, since many women discontinue orals after a few months, early use by breast-feeding women provides protection when it is least needed and may result in no protection later, when it is most needed. Oral contraceptives could, however, be provided soon after delivery with instructions to begin their use later.

### Postpartum IUD Insertion

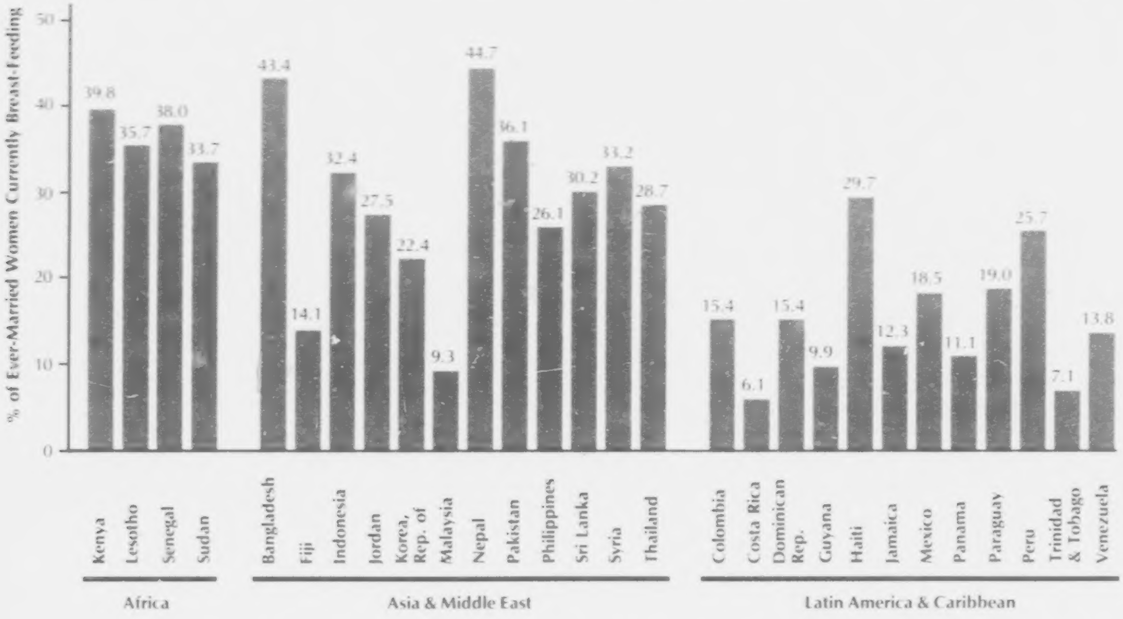
Some contraceptive methods are more appropriate for use immediately postpartum. IUDs, for example, have many advantages for women who deliver their babies in a hospital or health center and want to use a highly effective method immediately. Postpartum IUD insertion is safe and convenient (483). IUDs seem to have no effect on lactation. Comparing IUD users and women using no contraception, two studies found longer breast-feeding by users (174, 293); one, shorter (79); one, no difference (454). No differences were seen in milk quantity (222) or infant growth (79) (see Table 10, p. J-566–567). Although it has been suggested that an IUD might influence lactation by stimulating oxytocin secretion, in fact no such increase has been found (174). The most recent studies have also found no increase in prolactin levels in IUD users (33, 520, 578), although two earlier reports did (157, 658). Also, IUDs do not appear to affect milk composition (222).

One disadvantage of IUD insertion immediately postpartum is that expulsion rates are somewhat higher then (483, 537, 582). Breast-feeding, however, appears to make no difference (103). To minimize expulsions, the International Fertility Research Program has developed postpartum IUDs with biodegradable sutures tied to the upper arm of the IUD. These help to keep the device in place while the uterus resumes its normal nonpregnant size. Then the sutures gradually dissolve (532). Even if devices are expelled, however, many women return for reinsertion (140, 537, 683). Once in place, the IUD is an effective method of contraception, and an average of 70 to 80 percent remain in place for at least one year. After menses resume, however, heavy bleeding in some women with nonmedicated IUDs may contribute to anemia. (See **Population Reports**, *IUDs—Update on Safety, Effectiveness, and Research*, B-3, May 1979).

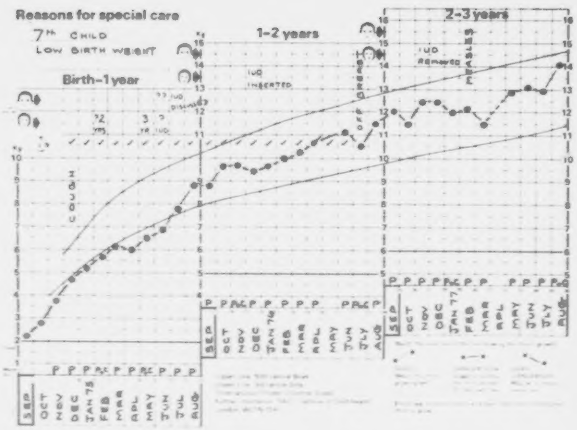
### Postpartum Sterilization

Voluntary sterilization is an appropriate postpartum method of fertility control for breast-feeding women who deliver in hospitals or health centers and want permanent protection against another pregnancy. Postpartum sterilization has been practiced throughout the world for decades without reported adverse effects on breast-feeding. One study, involving 36 women, has been published specifically on the effects of voluntary sterilization on breast-feeding (137). Women who were sterilized within 24 hours after delivery produced milk in

**Figure 8. Percentage of Ever-Married Women Currently Breast-Feeding in 28 Countries, World Fertility Survey Data**



Note: This figure reports the percentage of ever married women breast-feeding at the time of the survey. Women were age 15–49 except in Costa Rica, Panama, and Venezuela, 20–49. Source: Ferry & Smith (150)



**This sample growth chart shows that the infant, a seventh child, weighed less than normal at birth but after about a year reached and remained in the normal range.** (Courtesy of David Morley) (391)

quantities similar to those of the unsterilized control group, but women sterilized four to six days after delivery produced less milk for as long as two weeks postpartum. This suggests that an adverse effect may occur—perhaps because of anesthesia—if sterilization takes place at the time when milk production is beginning. More studies of this possibility would be useful. If such an effect exists, it could be minimized by using regional or local anesthesia at the lowest effective level.

At a point just after delivery, when a woman is beginning breast-feeding, may be an opportune time for her husband to obtain a vasectomy (453). During the 2- to 3-month period after vasectomy that sperm remain in the male genital tract, a breast-feeding woman is likely to be infecund, and after that the couple will be protected. In areas where infant mortality is high, however, couples might choose to delay sterilization of either partner at least until the last child is safely weaned.

Postpartum checkups, usually recommended for about six weeks after delivery, provide a good opportunity both for contraceptive advice and for any help that may be needed with breast-feeding. In many developing countries women do not return for postpartum care, but, when they know that family planning services will be provided at that time, they are more likely to return, as the International Postpartum Family Planning Program showed (683). Still, one study has found that more than half of the women delivering in hospital who planned to return for a postpartum IUD insertion in fact did not return (140). Nevertheless, the postpartum check-up is an appropriate time for breast-feeding women to consider IUD insertion, fitting of a diaphragm, or starting use of barrier methods. Barrier methods or the practice of coitus interruptus (withdrawal) may be especially appropriate for breast-feeding women in cultures where sperm is thought to poison or contaminate breast milk (684).

Where prolonged sexual abstinence is practiced during breast-feeding, of course no methods of contraception are needed until sexual activity begins. Use of periodic abstinence (rhythm, or Natural Family Planning) is difficult for breast-feeding women (see **Population Reports,** *Periodic Abstinence: How Well Do New Approaches Work?*, I-3, September 1981). Even after menses resume, patterns of ovulation, and thus basal body temperature and cervical mucus, may be erratic, requiring extended periods of abstinence.

Throughout the postpartum period—and, in fact, even from the beginning of pregnancy—although the pregnant or breast-feeding woman has no immediate need for contraception, she is probably in closer contact with health personnel than at any other time. Therefore health personnel should make every attempt during this time both to encourage breast-feeding and to help women plan for adequate contraception later, when fertility returns.

### When to Begin Contraception

Another question with important program implications is: How long after delivery can a breast-feeding woman wait to use contraception and still be reasonably sure of avoiding another pregnancy? For the individual woman, this is an extraordinarily difficult question to answer. As noted (see Impact of Breast-Feeding on Fertility, p. J-539), the overall likelihood of becoming pregnant increases with such interrelated factors as (1) the length of time after delivery; (2) diminished infant suckling, which may in turn be caused by (3) the introduction of other food for the infant; (4) the resumption of menses; and (5) the resumption of normal ovulation. Of course, a woman's age and fecundity and her ability to use contraception are also important.

A mathematical evaluation of the optimal time to start contraception found substantial variation in the effect on fertility under different conditions (448, 449). If the period of postpartum infecundity is short, if a high proportion of first menstrual cycles are ovulatory, if fecundability is high, and if contraceptive continuation rates are high, then starting contraception soon after delivery is the best strategy. These conditions are most likely to apply to young urban women who tend to breast-feed for a shorter period than rural women and who are more likely to deliver in a hospital, where IUD insertion can be provided immediately or during a postpartum visit. For these women, starting contraception with an IUD no later than the first postpartum visit would be reasonable. As the duration of breast-feeding (and therefore of infecundity) increases, the effectiveness of starting contraception immediately postpartum depends largely on continuation rates.

A prospective Philippine field study of pregnancy rates after delivery illustrates these interrelationships (394, 422). Among 794 urban Philippine women, 76 percent breast-fed, and for an average of 10.3 months. Among these women, the overall pregnancy rate at one year after resumption of menses was lower for IUD users than for users of oral contraceptives primarily because IUD continuation rates were higher. This was the case even though most IUD users had the devices inserted immediately postpartum, while most users of the pill started several months *after* first menses. For the IUD users, there was about a 4-month period of unneeded protection, or overlap, before first menses, but because the continuation rate was high—79 percent at one year—the overall pregnancy rate was low. For the pill users, because continuation rates were low, the pregnancy rate was high even though on the average pill users did not start until five months postpartum.

In the rural areas of most developing countries, conditions are different. Breast-feeding is almost universal and, since most women give birth at home, postpartum sterilization or IUD insertion is not feasible. A field evaluation that included some consideration of the optimal time to start contraception was undertaken in Matlab Thana, Bangladesh (436), where virtually all women breast-feed and where the duration of postpartum amenorrhea averages about 18 months (241, 463). In one area women were advised to begin oral contraception at 6 months postpartum, and in another area, at 18 months or first menses, whichever came first. (Whether they followed this advice, especially with regard to starting at 6 months, is not certain.) Among women over age 30, who showed the largest decline in fertility, there was no difference in fertility rates between the two areas (436).

### At First Postpartum Menses?

Ideally, contraception should begin just before ovulation resumes, but in practice it is impossible for an individual woman to predict the start of normal ovulation. For most women, the first sign of returning fertility is first menses. Thus there is much justification for recommending that contraception start at that time. Certainly, after first menses any woman who wants to avoid pregnancy should be instructed to use contraception, whether she continues breast-feeding or not.

The longer breast-feeding continues, however, the greater the likelihood that ovulation will occur before first menses. In a Chilean study, among breast-feeding women who resumed menstruating 60 days or more postpartum, ovulation preceded first menses in 72 percent (434). Thus, if a woman waits until first menses to start contraception, she runs a steadily increasing risk of becoming pregnant.

Another disadvantage of delaying contraception until first menses is that contraceptive supplies and services may not be immediately available. Unless a woman already has contraceptive supplies at hand or unless field support services bring supplies to her quickly, the start of contraception may be delayed for several months. Depending on the length of time after delivery and the amount of suckling, the risk of becoming pregnant for the breast-feeding woman just after first menses may be almost as great as for the woman who is not breast-feeding.

### With Suckling and Feeding Changes?

The direction of current research suggests that the frequency and intensity of suckling influence the duration of infecundity (see pp. J-542–543). If suckling frequency is reduced from 10 feedings per day to 6, for example, or if night feeding is eliminated, this change may lead to ovulation. Thus, if a specific time can be identified when infant suckling patterns change considerably, that might be an appropriate time to start contraception.

An important influence on suckling patterns may be the introduction of supplementary food as a regular and substantial part of infant diet. Although the extent—and indeed the definition—of supplementation varies greatly in different cultures, recent evidence suggests that infant food supplementation influences infant suckling, which in turn influences prolactin levels, milk production, and eventually ovulation. As a result, food supplementation precedes ovulation more often than first menses does and therefore, as an indication for starting contraception, provides a greater margin of protection against pregnancy. Moreover, since food supplementation may imply a definite change in the behavior of the mother feeding her child, it might not be difficult, from a programmatic standpoint, to link that change with the start of contraception or with the shift from a less effective method to a more effective one. Where food supplementation is introduced at a time that can be clearly defined and is closely associated with changing patterns or schedules of infant suckling, as in Alan McNeilly and colleagues' studies in Scotland (376, 648), such a recommendation would be reasonable. Even with present limited

## BREAST-FEEDING DURING PREGNANCY

If breast-feeding women become pregnant, should they continue breast-feeding? Although pregnancy is one of the major reasons for stopping breast-feeding (242, 274, 482, 605), practices vary greatly, and there has been little research on what problems may be involved in breast-feeding during pregnancy.

Some women continue breast-feeding until the third trimester of pregnancy (94, 242, 353), and a few, even after another birth, so that the older and the younger child are breast-feeding "in tandem" (330). The WHO Collaborative Study showed that in rural areas of Ethiopia, Zaire, and Guatemala, 30 to 40 percent of pregnant women were still breast-feeding, and in rural and poor urban areas in India about 70 percent of pregnant women were breast-feeding (605). Other women believe that pregnancy changes the quality of breast milk and that continued breast-feeding may be harmful to the suckling child (242, 407, 482, 567). Therefore they stop breast-feeding when a new pregnancy occurs. Still others stop nursing because they believe their supply of breast milk has diminished (242, 482). In a study in Bangladesh, for example, over half of the women who stopped breast-feeding because of "insufficient milk" were pregnant (242). An abrupt end to breast-feeding because of pregnancy may be dangerous to the infant. In a Senegal study, death rates were twice as high for infants age 12 to 17 months who were weaned because their mothers were pregnant as for all infants weaned at that age for whatever reason (85).

Are there physiological reasons for breast-feeding to diminish during pregnancy? In the later months of pregnancy a woman's milk production may decrease due to the high level of circulating estrogens and progesterone (569). In a US study of 158 women who breast-fed throughout pregnancy, 13 percent noted a sharp decrease in their milk supply and 52 percent noted a gradual decrease. Thus two-thirds of the women perceived a reduction in milk volume in the first four months of pregnancy (660). Reduction of milk yield during pregnancy has been reported in rats and cattle (541).

It is not clear whether the composition of breast milk changes when a woman becomes pregnant, but no changes that would require an end to breast-feeding have been suspected. In a study in Zaire, H. J. Vis and P. H. Hennart found that the breast milk of pregnant women was similar to colostrum in composition, with higher levels of protein and lower levels of fats and lactose than the mature milk of nonpregnant women (567).

The main problem is the nutritional status of the mother. Ideally, both pregnancy and lactation require supplementation of the mother's normal diet. With adequate maternal supplementation, breast-feeding during pregnancy does not seem to be harmful, although very little research has been undertaken on the subject. Without adequate maternal supplementation, lactating women who are also pregnant face a heightened risk of malnutrition, which may also affect both the suckling child and the new pregnancy.

knowledge, child health workers and family planning personnel can point out the possible link between infant diet and maternal fecundity and thus the increased need for contraceptive protection after food supplementation begins.

Another consideration in advice about breast-feeding and contraception is the previous experience of the individual woman. If she has breast-fed before and can identify any consistent patterns in the length of postpartum amenorrhea or in suckling behavior or food supplementation, these should be taken into account in deciding when to start contraception (317). Although each infant will be different, the mother's own lactational and fertility experience, as well as the experience of the community (391), can be a useful guide as long as other conditions have not changed. More research is needed, both on different patterns of suckling and supplementation and on hormonal changes in the mother, before more specific recommendations can be made.

### Choice of Hormonal Contraceptive

For a breast-feeding woman who wants to avoid pregnancy but does not want to use nonhormonal methods or does not have easy access to them, a major concern is whether hormonal contraceptives can be used after lactation is established and, if so, which formulations are best and when use should start.

Because progestin-only contraceptives—in injectable, oral, or implant form—have not been shown to have any adverse effect on lactation and may augment milk production (see p. J-545), some experts recommend that progestins, rather than combined oral contraceptives, be used by breast-feeding women (262, 276, 481). Using progestin-only contraceptives during lactation would have the further advantage that any disruption in menstrual cycles due to the progestin might be expected and therefore less disturbing to the mother. It has also been suggested that women should start by using progestin-only compounds and then, at six months or after first menses, shift to combined pills for greater protection (481). Malcolm Potts has proposed that, to emphasize the preferability of progestins, progestin-only oral contraceptives be packaged with a picture of a breast-feeding infant, and the combined oral contraceptives, packaged with a picture of a woman and an older child (451). On the other hand, progestin-only oral contraceptives have higher failure rates and higher rates of break-through bleeding. These might not be serious problems during breast-feeding, but, after breast-feeding ends, a woman using progestin-only compounds might want to shift to a combined pill for greater effectiveness and menstrual regularity.

Because daily progestin-only pills or progestin implants may minimize and delay the transfer of any steroids to the infant, they theoretically have an advantage over injection as a means of administration. Whether or not the larger milk volume reported with DMPA, the mostly widely used injectable, means an increase in nutrients or outweighs any potential dangers of steroid transmission to the infant is not known.

In practice, however, progestin-only contraceptives are not widely available. Implants are still in the experimental stage (511). Only two progestin-only injectables, DMPA and NET EN, have been approved for use in a substantial number of countries, and some questions remain in dispute about other aspects of their acceptability and safety (see **Population Reports,** *Injectable Progestogens—Officials Debate but Use Increases,* K-1, March 1975).

**Table 11. Retail Pharmacy Purchases of Progestin-Only Oral Contraceptives in Selected Countries, 1978–1981**
(in thousands of cycles)

| | 1978 | 1979 | 1980 | Jan.-June 1981 |
|---|---|---|---|---|
| **DEVELOPED AREAS** | | | | |
| **Australia** | 333.4 | 353.0 | 381.6 | 208.9 |
| **Austria** | 6.8 | 6.9 | 6.9 | 4.3 |
| **Belgium** | 92.2 | 95.2 | 102.8 | 54.3 |
| **France** | 199.8 | 633.3 | 848.7 | 518.5 |
| **Germany** | 320.6 | 334.7 | 337.1 | 173.9 |
| **Greece** | 0.3 | 1.9 | 0.3 | 0.0 |
| **Japan**[a] | 24.6 | 26.9 | 21.2 | 8.5 |
| **Netherlands**[b] | 125.1 | 105.4 | 85.4 | 36.0 |
| **Portugal** | 12.5 | 15.9 | 21.9 | 11.0 |
| **South Africa** | 62.2 | 60.9 | 62.6 | 32.8 |
| **Spain** | 22.1 | 17.1 | 13.8 | 3.0 |
| **United Kingdom** | 642.3 | 1,079.1 | 1,527.8 | 814.3 |
| **United States** | 183.7 | 184.0 | 273.5 | 134.0 |
| **Subtotal** | 2,025.6 | 2,914.3 | 3,683.6 | 1,999.5 |
| **DEVELOPING AREAS** | | | | |
| **Argentina** | 147.8 | 147.5 | 170.5 | 104.1 |
| **Brazil** | 424.1 | 451.0 | 583.1 | 259.0 |
| **Mexico** | 95.3 | 93.3 | 80.5 | 41.5 |
| **Subtotal** | 667.2 | 691.8 | 834.1 | 404.6 |
| **TOTAL** | 2,692.8 | 3,606.1 | 4,517.7 | 2,404.1 |

[a] Japan—data gathered at wholesale level

[b] Netherlands—includes all outlets, not just pharmacies

Source: IMS International study prepared for the Population Information Program, 1981

Oral progestins, although approved for use in many countries and gaining in popularity, have not yet been widely adopted and may be difficult to obtain (see **Population Reports,** *Minipill—A Limited Alternative for Certain Women,* A-3, September 1975). During the last three years sales of progestin-only oral contraceptives have nearly doubled in the major sales areas, increasing from 2.7 million cycles in 1978 to almost the same quantity in just the first six months of 1981 (see Table 11)(650). The largest increases have occurred in France, where progestin-only pills constitute about 3 percent of all OC sales, and Britain, where they constitute 7 percent. In developing countries, however, where these formulations would be especially suitable because of the large number of women breast-feeding, sales have increased much less, and they are not generally available through family planning programs. USAID is hoping in 1982 to purchase and provide progestin-only pills on a limited basis for family planning programs.

### Use of Combined Orals

At present, the issue of whether or when family planning programs should recommend or distribute combined oral contraceptives for breast-feeding women remains unresolved. The estrogen and progestin doses in combined pills have been reduced below the levels used in many early studies, with some reduction in the effects on breast milk. Moreover, all major studies using low-dose formulations, including the most recent, have found no significant effect on infant weight gain (79, 240, 288), even if volume of breast milk is diminished. A detailed 1981 nutritional study of breast milk components showed that milk volume, lactose, nitrogen, and several specific milk proteins all were altered by oral contraceptive use, but all remained within the normal range (345). In 1976 the International Pediatric Association warned that "contraceptive pills containing substances that are likely to suppress lactation or which may adversely affect the infant if excreted in breast milk must not be distributed to lactating women" (261). But the most recent statement of the American Academy of Pediatrics, Committee on Drugs, which was endorsed by the American College of Obstetricians and Gynecologists, Committee on Obstetrics, Maternal and Fetal Medicine, concludes that previous recommendations are "confusing," that "no unique effect of steroidal contraceptives on nursing mothers has been confirmed," and that in each case "an informed, individualized, and effective choice" should be made (20). National family planning and maternal and child health programs, no less than private physicians, need to be responsive to the needs and concerns of individual women.

Combined estrogen-progestin pills are one of the most widely used and preferred contraceptive methods, especially among younger women (see **Population Reports,** *OCs—Update on Usage, Safety, and Side Effects,* A-5, January 1979). They are readily available through family planning programs in many countries. A 1978 international survey of the practices of 754 physicians working with family planning associations in 65 countries shows that a high percentage of physicians have prescribed oral contraceptives for breast-feeding women (475, 523). Except in North America a high proportion also have prescribed progestin-only pills or injectables.

| | % Ever Prescribing to Breast-Feeding Women | | |
|---|---|---|---|
| Area | Combined Oral Pills | Progestin-Only Pills | Progestin-Only Injections |
| **Africa** | 88 | 34 | 76 |
| **Asia** | 71 | 22 | 73 |
| **Latin America** | 63 | 27 | 36 |
| **Europe** | 40 | 67 | 52 |
| **Oceania** | 30 | 89 | 69 |
| **North America** | 26 | 19 | 9 |

The survey, conducted jointly by the IPPF and the United States Centers for Disease Control, also showed that more than half of the physicians in all regions provided voluntary sterilization, IUDs, and barrier methods to breast-feeding women (except for a lower percentage of European physicians providing sterilization). The major reason for providing combined oral contraceptives was the preference of the user, followed by the previous lactational history and use of feeding supplements. Less important were IPPF guidelines, regional or national policy, and local clinic policy. About 19 percent had received complaints about decreased milk production from women using combined orals, compared with 1 to 2 percent receiving complaints from women using IUDs or progestin-only pills or injectables (475, 523).

A review of World Fertility Survey data from 14 countries shows that from one to 10 percent of breast-feeding women use oral contraceptives, except in Indonesia, where 20 percent of breast-feeding women use orals (432) (see Table 12). In general, women using orals tend to be younger, to live in urban areas (except in Indonesia), to be better educated, and to have had more live births. Generally, women who have breast-fed longer are more likely to be using orals, suggesting that most women wait for some months postpartum before starting pills. In four countries, however—Costa Rica, Fiji, Indonesia, and Jamaica—5 percent or more of women at some point during the first three months of breast-feeding were using orals (432). In a study of over 2,000 women in Lagos, 7 percent—almost half of all those who had used contraception—had taken orals while breast-feeding their last child (406, 661).

The WHO Collaborative Study on Breast-feeding, although not involving strictly representative samples, shows that, among the women in various countries surveyed who were using oral contraceptives, 18 to 40 percent began while still breast-feeding. Up to 23 percent began before their breast-feeding child was three months old (605). This is hardly surprising, since 10 to 25 percent were menstruating by three months (see Figure 6, p. J-539).

There are at least two reasons that family planning and health centers provide oral contraceptives in spite of unresolved questions about adverse effects. First, there is the danger that if women want to use orals and are advised they cannot do so while breast-feeding, they may discontinue breast-feeding in order to use orals. As Franz Rosa observes, forcing women to make this choice has "disasterous implications for infant health in areas where there are no suitable alternatives to breast-feeding" (481). Although no systemmatic research has been undertaken on this issue, there is some evidence that women do stop breast-feeding in order to start oral contraception (479, 482, 625).

Second, without contraception, one of the greatest health risks a woman faces even during early breast-feeding is pregnancy. The adverse effects of closely spaced births on both mother and child have been fully documented (141, 352, 461). In most cases pregnancy appears to diminish the supply of breast milk (see box, p. J-553). These hazards must be weighed against any potential risk of using oral contraceptives. Moreover, over time, as the risk of pregnancy increases, any risks to the child of using hormones diminish because breast milk becomes a smaller part of the diet.

### Table 12. Percentage of Ever-Married Women Currently Breast-Feeding, by Contraceptive Use, in 14 Developing Countries, World Fertility Survey Data, 1975–1978

| Region, Country & Survey Date | % Currently Breast-Feeding | % Currently Breast-Feeding and Using: | | | | % Currently Using Contraception |
|---|---|---|---|---|---|---|
| | | Any Method | Pill | Injection | IUD | |
| **AFRICA** | | | | | | |
| **Kenya 1977** | 40.1 | 2.1 | 0.7 | 0.0 | 0.1 | 6 |
| **ASIA & MIDDLE EAST** | | | | | | |
| **Bangladesh 1975–76** | 43.5 | 4.1 | 1.7 | 0.2 | 0.1 | 7 |
| **Fiji 1974** | 14.1 | 5.9 | 0.9 | 0.1 | 0.4 | 39 |
| **Indonesia 1976** | 32.4 | 10.7 | 6.5 | 0.1 | 1.6 | 23 |
| **Jordan 1976** | 27.5 | 3.8 | 1.6 | 0.2 | 0.3 | 24 |
| **Korea, Rep. of 1974** | 22.5 | 4.7 | 1.2 | 0.0 | 1.3 | 32 |
| **Sri Lanka 1975** | 30.1 | 10.4 | 0.5 | 0.1 | 1.7 | 29 |
| **LATIN AMERICA & CARIBBEAN** | | | | | | |
| **Colombia 1976** | 15.4 | 3.8 | 0.9 | 0.0 | 0.6 | 37 |
| **Costa Rica 1976** | 6.1 | 2.9 | 0.6 | 0.1 | 0.1 | 58 |
| **Dominican Rep. 1975** | 15.4 | 2.5 | 0.4 | 0.0 | 0.2 | 27 |
| **Guyana 1975** | 9.9 | 2.1 | 0.5 | 0.0 | 0.3 | 29 |
| **Jamaica 1975–76** | 10.8 | 3.3 | 0.8 | 1.0 | 0.0 | 35 |
| **Panama 1976** | 11.1 | 2.8 | 0.6 | 0.0 | 0.1 | 48 |
| **Peru 1977–78** | 25.7 | 5.0 | 0.3 | 0.1 | 0.1 | 28 |

Note: Women were age 15-49 except in Costa Rica and Panama, 20-49. In Latin America and the Caribbean "married" includes legal and informal marriages.

Source: adapted from Pebley & Menken (432); % currently using contraception from Carrasco (637).

If, for whatever reason, combined oral contraceptives are used, several precautions might be advisable to minimize the risk of a reduction or other change in milk supply. Both clinic-based family planning workers and those involved in community-based distribution of combined estrogen-progestin pills should advise breast-feeding women:

1. Use the lowest available dose.
2. Do not initiate combined pills until lactation is well-established—at least two or three months postpartum. In a traditional rural society, six months postpartum might be the earliest date to consider initiating use unless menses resume earlier, and an even later date may be more appropriate in some settings where breast-feeding is prolonged and supplementation minimal.
3. Take each oral contraceptive tablet daily at the beginning of the longest interval between breast-feedings.
4. Provide additional suckling time when oral contraceptive use begins in order to help counteract any hormonal ef-

## RESEARCH NEEDS

Both breast-feeding and family planning can be vital elements in improving maternal and child health. Among the many areas where more knowledge and new research would be useful are:

### General and Basic Research

- The physiology of breast-feeding, including the hormonal basis for infecundity and hypothalamic function.
- Improved means of measuring milk quantity, milk composition, and suckling behavior that would be more accurate and/or make larger studies more feasible (330). Nonradioactive heavy water is one possibility for assessing the infant's daily milk intake (106).
- Effects of maternal nutrition on the quality and composition of breast milk.
- Effects of breast-feeding on the health of the mother, especially if she is poorly nourished.
- Adaptive mechanisms that may function in poorly nourished women to support lactation (347, 456).
- Development of growth standards for breast-fed infants.
- Optimal time to introduce supplementary foods for the infant under different circumstances.
- Breast-feeding patterns and the return of ovulation: how precisely can the aspects of breast-feeding that control the return of ovulation be defined? A few detailed studies are underway (260, 376). Also, several studies are being planned to see if measures of frequency of suckling and other breast-feeding behavior can be used to predict the return of ovulation for individual women (75, 185).

### Research for Policy

- Current trends of breast-feeding in urban and rural areas throughout the world.
- Health and economic impact of breast- and bottle-feeding under different conditions.
- Reasons that women continue or discontinue breast-feeding. The Population Council, for example, is beginning a detailed survey of breast-feeding in Colombia, Indonesia, Kenya, and Thailand (680). A prospective study in the Philippines will explore the decision-making processes of low-income urban women with respect to infant feeding (669).
- Evaluation of the ways in which current scientific knowledge on various types of infant feeding is disseminated to health professionals (70).
- Evaluation of present medical, hospital, and health policies that affect breast-feeding.
- Evaluation of programs and policies to promote breast-feeding and discourage bottle-feeding.
- Evaluation of food supplementation programs for breast-feeding mothers: what are their effects on maternal health and child growth?

### Research for Family Planning Programs

- Contraceptive practice of breast-feeding women and beliefs about fertility and sexual behavior while breast-feeding, so that programs can appeal specifically to breast-feeding women.
- When to initiate contraception, considered in terms of program effectiveness: what program strategies will yield the greatest health benefit and fertility reduction? WHO is testing various times to initiate different oral formulations in order to measure continuation rates and program effectiveness (635).
- Effects of family planning policies on breast-feeding—for example, do women stop breast-feeding in order to obtain pills from programs that will not provide them to breast-feeding women?

### Research on Breast-Feeding and Contraception

- Differences between breast-feeding and non-breast-feeding women in the effectiveness, benefits, and risks of each contraceptive method, including voluntary sterilization. Differences among breast-feeding women by time of contraceptive initiation also need study. All new contraceptives should eventually be tested for breast-feeding as well as for non-breast-feeding women.
- Effects of various contraceptive methods on breast-feeding. More careful research is needed on the specific hormonal contraceptives currently in use and their effects on breast milk volume, milk composition, and hormone transmission in milk, including possible short- and long-term effects on the breast-fed child.
- Practical and reliable methods of identifying the first postpartum ovulation, to serve as a basis for more accurate advice on when modern methods of contraception should be initiated.
- The possibility of safe, systemic contraceptive methods that reinforce breast-feeding, assuring infecundity and promoting lactation at the same time. Drugs under consideration are thyrotropin releasing hormone (TRH), sulpiride, metaclopramide, and chlorpromacine, all of which raise prolactin levels but may have adverse effects as well (33, 376, 545, 550). TRH has increased milk production in some studies (283, 549, 550) but not in others (620, 623). Hyperthyroidism is a side effect of high doses (550). Sulpiride increased milk production in an Egyptian study, but its contraceptive effect was judged not adequate (33).

fect in reducing milk supply. If oral contraceptives are first taken at the same time that supplemental foods are added to the infant diet, a decline in milk supply should be expected, but breast-feeding can still be maintained. Breast milk will continue to benefit the child after other foods are introduced and after menses resume.

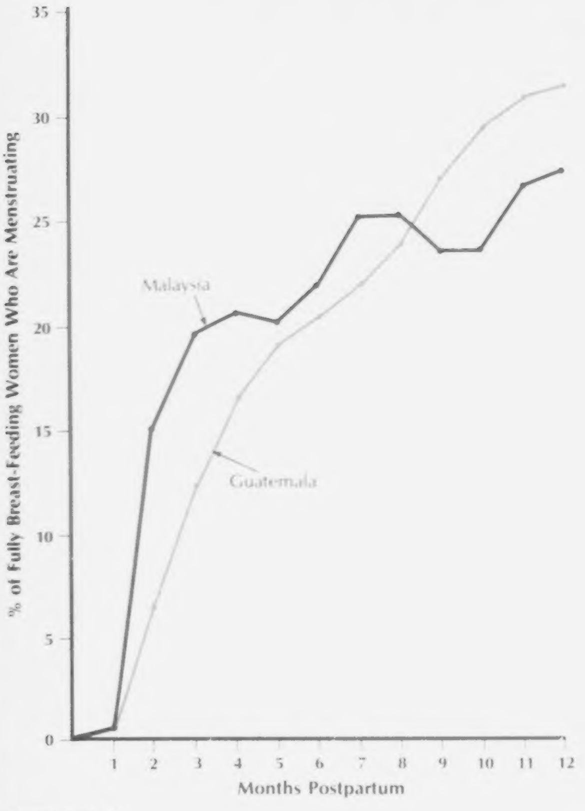
5. Encourage breast-feeding women who start the pill to continue for nine months or longer (50), since continuation rates strongly influence long-term effectiveness.

Above all, family planning and health workers should be sure that breast-feeding women know three important facts:

- that breast-feeding is the best way to protect infant health and, even after food supplementation begins, remains an important element of infant nutrition,
- that the amount of infant suckling is the strongest influence on the amount of breast milk,
- that, after three to six months, depending on breast-feeding practices, and particularly after menses resume, breast-feeding does not provide adequate protection against pregnancy, and effective contraception is needed.

Family planning workers can help breast-feeding women by encouraging them to continue breast-feeding and by keeping women's personal choice and concerns about breast-feeding in mind when providing family planning services.

**Figure 9. Percentage of Fully Breast-Feeding Women Who Have Resumed Menstruating, by Month Postpartum, Guatemala and Malaysia**



Source: Butz (71)

**Among fully breast-feeding Guatemalan and Malaysian women, about 20 percent were menstruating at six months, a sign that many women have a real need for contraception while breast-feeding.**

## Options for Family Planning Programs

These suggested policies are offered as reasonable options, based on current knowledge:

- All women should be encouraged to breast-feed their children initially and for as long as feasible.
- Extra food for the mother should begin at the start of pregnancy and continue throughout lactation to help maintain the mother's nutritional status and perhaps also to improve her breast-feeding performance.
- Breast milk alone is usually sufficient for the infant until four to six months of age if the mother is adequately nourished. After four to six months an infant should receive supplemental feedings.
- A **fully** breast-feeding woman usually does not need contraception before six months postpartum. Sometimes, however, IUD insertion or voluntary sterilization can be performed just after delivery. Supplies and instructions for other methods can be provided then or at a postpartum checkup.
- To minimize any adverse impact on milk volume or length of lactation, or any drug transfer, progestin-only pills may be the best hormonal method, followed by injectables or the lowest available dose of combined pills (0.05 mg or less estrogen). The US Agency for International Development (USAID) plans a limited purchase of progestin-only pills in 1982. Where progestin-only methods are not available, the advantages of low-dose combined pills in preventing another pregnancy—with its reduction in milk supply and strain on maternal health—may outweigh any potential disadvantages.
- No universal rule is possible to determine when a breastfeeding woman can start hormonal methods. A woman who allows frequent suckling day and night with little supplementation and is not menstruating might reasonably wait 12 or 18 months to start combined pills or might start progestin-only methods earlier. A woman on a 3- to 4-hour, day-only feeding schedule who gives the infant other food early might reasonably start two or three months after delivery.
- Waiting for first menses involves some risk of pregnancy, but after first menses effective contraception is essential. Supplies and instructions should be ready in advance.
- To maintain adequate milk supply, frequent suckling should be encouraged. When mothers start hormonal contraceptives, they should be cautioned about changes in their activities that might interfere with the frequency and duration of suckling.
- Family planning programs should provide a range of methods, including hormonal and nonhormonal methods, for breast-feeding women. Programs that either do not offer nonhormonal methods or discourage use of hormonal methods during lactation may increase the risk that women will stop breast-feeding in order to use the method which is available or preferred or, alternatively, that they will become pregnant while breast feeding.

## TABLES

Note: Studies were included in Tables 3–6 if they involved at least 20 women in each group using hormonal contraceptives, included a comparison group, and specified the hormonal components of the contraceptive. Unless otherwise stated, contraceptive was administered orally. Levonorgestrel and *d*-norgestrel are the same compound, as are norethindrone and norethisterone.

**EE = ethinyl estradiol; ME = mestranol; DMPA = depot medroxyprogesterone acetate (Depo-Provera);**
**NET EN = norethindrone enanthate (Noristerat).**

### Table 3. Selected Studies of Combined Estrogen-Progestin or Estrogen-Only Contraceptives That Found No Impact or Beneficial Impact on Breast-Feeding Performance

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Begun within one week postpartum** | | | | | | | |
| **Toaff et al. 1969** (538) **Israel** | EE 0.3 (estrogen only) | 66 | 1 day | 5 days | 46 placebo users;<br>63 using progestin-only OC (see Table 5).<br>(Pills randomly allocated, double-blind.) | Milk quantity by test weighing | NSS |
| **Begun at various times postpartum** | | | | | | | |
| **Semm 1966, Semm & Dittmar 1966** (502, 503) **West Germany** | Lynestrenol 2.5 + ME 0.075 (Lyndiol 2.5) | 50<br>35 | 1 day<br>10 days | 1 month | Placebo users, 50 in 1-day group, 35 in 10-day group (randomly allocated, double-blind) | Milk quantity by test weighing | For OC and placebo begun 1 day postpartum, NSS. Begun at 10 days, quantity somewhat higher with OC than with placebo. |
| **Begun more than one week postpartum** | | | | | | | |
| **Campodonico et al. 1978** (79) **Chile** | Levonorgestrel 0.15 + EE 0.03 (Nordette) | 60 | 25–30 days | 3 months | 45 IUD users (Lippes Loop or Copper T) (see Table 10);<br>45 noncontraceptors. | Infant weight gain;<br>% still breast-feeding;<br>% still fully breast-feeding. | Weight gain, NSS.<br>Lower % with IUD (SS).<br>NSS |
| **Garcia et al. 1963** (164) **Puerto Rico** | Norethynodrel 2.5 + ME 0.1 (Enovid) | 34 | 3 weeks | NR | Previous breast-feeding experience. Also studied: 187 users of higher OC doses (see Table 4). | Mothers' impressions of lactation | NSS |
| **Guiloff et al. 1974** (195) **Chile** | Norethindrone 1.0 + EE 0.05 | 40 | 30 days | ≥ 10 months | Previous breast-feeding experience of all 385 participants using various contraceptive methods, randomly assigned (see Tables 4, 5, and 10). | Median duration of breast-feeding | NSS |
| **Prema 1981** (454) **India** | *d*-Norgestrel 0.15 + EE 0.05<br>*d*-Norgestrel 0.15 + EE 0.03 | 52<br>50 | ≥ 6 months | 3 years | 1,917 noncontraceptors;<br>55 sterilized women;<br>68 IUD users (see Table 10);<br>73 using progestin-only injectables (see Table 6).<br>Also, previous breast-feeding experience. | Duration of breast-feeding;<br>Mothers' impressions of breast milk output during first month of contraceptive use. | Duration of breast-feeding similar for all groups and similar to previous experience. No abrupt decrease in milk output observed during first month of use. |

### Table 4. Selected Studies of Combined Estrogen-Progestin Contraceptives that Found Adverse Impact on Breast-Feeding Performance

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Begun within one week postpartum** | | | | | | | |
| **Kaern 1967** (288) **Denmark** | Norethisterone 1.0 + ME 0.05 (Norinyl 1) | 212 | 1 day | 7 days | 206 placebo users (pills randomly allocated, double-blind) | % starting breast-feeding;<br>Mothers' impressions of need for supplementary feeding;<br>Infant weight gain. | NSS<br>Higher for OC users (SS)<br>NSS |

NR = not reported    NSS = difference not statistically significant    SS = difference statistically significant

**Table 4 continued**

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Begun more than one week postpartum** | | | | | | | |
| **Garcia et al. 1963** (164) **Puerto Rico** | Norethynodrel 19.7 + ME 0.3<br>Norethynodrel 9.85 + ME 0.15<br>Norethynodrel 5.0 + ME 0.075 | 22<br>37<br>84 | 3 weeks | NR | Previous breast-feeding experience | Mothers' impressions of lactation | % stating that they lactated less than previously increased with the dose. (No effect at dose of norethynodrel 2.5 + ME 0.1 (see Table 3).) |
| **Gomez-Rogers 1967** (174) **Chile** | Norethisterone acetate 1.0 + EE 0.05 (Minovlar)<br>Chlormadinone acetate 1.5 + ME 0.08 (sequential) | 40<br>52 | 1–2 months | ≥ 10 months | 150 noncontraceptors; 81 IUD users (see Table 10); 103 using progestin-only injectables (see Table 5). Also, previous breast-feeding experience. | Median duration of breast-feeding | Duration significantly shorter for both OC groups than for their previous experience and shorter than for all comparison groups. |
| **Guiloff et al. 1974** (195) **Chile** | Quingestanol acetate 5.0 + quinestrol 2.0 (monthly)<br>Quingestanol acetate 2.5 + quinestrol 2.0 (monthly)<br>Chlormadinone 1.5 + ME 0.08 (sequential) | 194<br>81<br>52 | 30 days | ≥ 10 months | Previous breast-feeding experience of all 385 participants using various contraceptive methods, randomly assigned. (See Tables 3, 5, and 10.) | Median duration of breast-feeding | Duration significantly shorter than combined previous experience |
| **Gupta et al. 1974, 1977** (197, 198) **India** | Norgestrel 0.5 + EE 0.05 (Primovlar)<br>Norethisterone acetate 1.0 + EE 0.05 (Minovlar) | 34<br>30 | 6 weeks | 4.5 months | Nonhormonal group: 28 using female sterilization and 14 using other methods; 30 using progestin-only OCs (see Table 5). (Pills allocated according to women's endocrine profiles.) Pretreatment experience. | Milk quantity by test weighing and breast pump; Number of supplementary feedings. | Significant reduction in milk quantity for women using the 2 combined pills but not for the progestin-only and nonhormonal groups. More supplementary feedings by users of combined pills. |
| **Huber et al. 1980** (240) **Bangladesh** | Norethindrone 1.0 + ME 0.05 (Noriday 1 + 50) | 85 | 6–18 months (mean 6.8 months) | 4 months (mean duration of use 9.4 months) | Nonhormonal group: 76 users of female sterilization and 27 using other nonhormonal methods or no contraception; 75 using progestin-only injectable (see Table 5). | Weight for age; Weight for length; Mothers' impressions of breast milk quantity; Number of supplementary feedings per day; 24-hour breast milk quantity and caloric content for some. | Weight for length increased in all 3 groups, with weight gain for OC group intermediate between nonhormonal group (low) and injectables group (high). Reduced milk quantity and more supplementary feedings in OC group. Calorie differences NSS. |
| **Ibrahim & El-Tawil 1968** (254) **Egypt** | Ethynodiol diacetate 0.5 + ME 0.1 (Ovulen 0.5) | 47 | 1–4+ months | 6 months | Comparison among times pill use began | Duration of lactation | Duration of lactation shorter in women who initiated pill use earlier. |
| **Kamal et al. 1969** (291) **Egypt** | Lynestrenol 2.5 + ME 0.075 (Lyndiol 2.5)<br>Lynestrenol 1.0 + ME 0.1 (Lyndiol 1.0)<br>Dihydroxyprogesterone acetophenide 150 + estradiol enanthate 10 (injection) | NR | 6–10 weeks | Up to 32 weeks | Unreported number using progestin-only OC (lynestrenol 0.5) or IUD plus placebo (see Tables 5 and 10); Previous breast-feeding experience. (Double-blind: 120 participants in study.) | Infants' growth curves. Age at supplementation and weaning; Women's impressions of breast size and fullness and of adequacy of milk supply; Milk quantity by test weighing and breast pump; Feed-to-weight adequacy. | Growth curves, NSS. Other measures gave inconsistent results. Milk yields rose and then declined for lynestrenol 2.5 + ME 0.075, and declined steadily for all others. Performance ranked best-to-worst: placebo, lynestrenol 1.0 + ME 0.1, injection, lynestrenol 2.5 + ME 0.075. |

NR = not reported NSS = difference not statistically significant SS = difference statistically significant

**Table 4 continued**

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Koetsawang et al. 1972** (312) **Thailand** | Ethynodiol diacetate 1.0 + ME 0.1 (Ovulen)<br>Chlormadinone acetate 2.0 + ME 0.08 (C-Quens) | 20<br>20 | 6 weeks | 16 weeks (10 weeks use) | 20 using nonhormonal contraception | Milk quantity by breast pump; Infant weight gain. | Weight gain and milk volume less than in controls (SS).<br>Weekly weight gain:<br>Ovulen 147 g<br>C-Quens 180 g<br>Controls 202 g<br>Volume at 16 weeks:<br>Ovulen 37 ml<br>C-Quens 56 ml<br>Controls 82 ml |
| **Kora 1969** (316) **India** | Ethynodiol diacetate 1.0 + ME 0.1 (Ovulen) | 62 | 4–24 weeks | 2 months | 15 using nonhormonal contraception. Pretreatment experience, analyzed by age of infant. | Milk quantity by test weighing; Infant weight gain. | Both criteria less for OC users than for nonusers or pretreatment group (SS). |
| **Miller & Hughes 1970** (381) **US** | Norethindrone 1.0 + ME 0.08 | 24<br>23 | 2 weeks<br>6 weeks (after placebo for days 14–34) | 3 months<br>2 months | 48 using nonhormonal contraception; Pretreatment experience of 23 who started with placebo but were switched to OCs. (Random allocation of OC initiation time (2 or 6 weeks), double-blind.) | First 6 weeks: milk volume by test weighing; infant weight gain; supplementary feeding (number of calories).<br>First 3 months: duration of breast-feeding; inadequate milk supply as reason for stopping breast-feeding. | Maternal milk production during first 6 weeks (as assessed by all three methods) was less for OC than for placebo group: 15% less milk, 3 oz. less weight gain in 5th week.<br>% still breast-feeding at 3 months highest for control group, lowest for those starting OCs 2 weeks postpartum. Inadequate milk cited by more OC users. |

**Table 5. Selected Studies of Progestin-Only Contraceptives That Found No Impact or Beneficial Impact on Breast-Feeding Performance**

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Begun within one week postpartum** | | | | | | | |
| **Agoestina & Biben 1976** (17) **Indonesia** | DMPA 150 (Depo-Provera) 3-month injection) | 100 | 2–4 days | 12 weeks | 75 not using hormonal contraception | Milk quantity by breast pump | Milk quantity greater than for controls. |
| **Badraoui et al. 1977** (631) **Egypt** | DMPA 300 (monthly injection)<br>Dihydroxyprogesterone acetophenide 150 (monthly injection) (Deladroxone)<br>Quingestanol acetate 0.3<br>Chlormadinone acetate 0.5 | 25<br>25<br>25<br>25 | ≤ 2 hours | 1 year | 238 diaphragm users and noncontraceptors evaluated in earlier study (221) | Milk quantity by breast pump; Infant weight gain. | Milk quantities similar for all 4 treatment groups.<br>Infant weights within normal range for all groups; highest with DMPA and dihydroxyprogesterone acetophenide. |
| **Casares Ponce 1969** (88) **Mexico** | Chlormadinone acetate 0.5 | 25 | 2 days | 6 months | Infant weight standards of Mexican Academy of Pediatrics | Infant weight gain Mothers' | Weight gain similar to standards. |
| **Koetsawang et al. 1972** (313) **Thailand** | DMPA 150 (Depo-Provera) (3-month injection) | 30 | 2–4 days | 16 weeks | 25 using nonhormonal contraception | Milk quantity by breast pump;<br>Infant weight gain;<br>Mothers' impressions. | Quantity greater (SS).<br>NSS<br>Excess milk reported by 1/2 users, none of controls. |

NR = not reported

NSS = difference not statistically significant

SS = difference statistically significant

**Table 5 continued**

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Ruiz-Velasco et al. 1979** (487) **Mexico** | NET EN 200 | 75 | 2 days | 3 months | Previous breast-feeding experience | Mothers' impressions of milk quantity | In $^{1}/_{2}$, NSS; in > $^{1}/_{3}$, increase over previous experience. |
| **Toaff et al. 1969** (538) **Israel** | 6-α-methyl-17-α-hydroxy-progesterone acetate 30 | 63 | 1 day | 5 days | 46 placebo users; 66 using estrogen-only OCs (see Table 3) (Pills randomly allocated, double-blind.) | Milk quantity by test weighing | NSS |
| **Begun at various times postpartum** | | | | | | | |
| **Guiloff et al. 1974** (195) **Chile** | DMPA 250 (6-month injection) | 80<br>33 | 1–2 days<br>30 days | ≥ 10 months | Previous breast-feeding experience of all 385 participants, using various contraceptive methods, randomly assigned (see Tables 3, 4, and 10). | Median duration of breast-feeding | With DMPA at 1-2 or 30 days, duration longer than previously (SS). Duration less when begun postpartum than at 30 days, but still longer than controls. Others NSS. |
| | Chlormadinone acetate 250 (3-month injection) | 54 | 30 days | | | | |
| | Quingestanol acetate 0.3 | 81 | 30 days | | | | |
| **Karim et al. 1971** (298) **Egypt** | NET EN 200 (Noristerat) (3-month injection) | 68<br>57 | 7 days<br>6 weeks | 6 months | 100 users of nonhormonal contraception | Infant weight gain;<br>Milk quantity by test weighing and breast pump. | Milk volume and weight gain significantly greater for all treatment groups than for controls. (No supplementary food). Initiation time, NSS. |
| | DMPA 150 (Depo-Provera) (3-month injection) | 51<br>55 | 7 days<br>6 weeks | | | | |
| **Seth et al. 1977** (504) **India** | NET EN 40 (implant) | 23<br>12 | 6 days<br>6 weeks | 8 months | 15 using nonhormonal contraception;<br>Previous breast-feeding experience. | Infant weight gain;<br>Duration of lactation;<br>Supplementary feeding. | Weight gain and duration compared with nonusers, NSS.<br>Duration shorter than previously in NET EN group, longer in controls.<br>More feeding by early NET EN group at 3 mo. (SS); NSS later. |
| **Zañartu et al. 1976** (621, 622) **Chile** | DMPA 150 (Depo-Provera) (3-month injection) or 250–300 (6-month injection) | 133<br>206<br>67 | ≤ 1 month<br>1–3 months<br>4–6 months | Up to 18 months | 173 IUD users and noncontraceptors participating in study of breast-feeding education | Duration of breast-feeding | Longer for both hormonal contraceptive groups than controls (SS). Longer when first injection was at 4–6 months. |
| | Chlormadinone diacetate 0.6 (Clogestone) | 100 | 3–10 months | | | | |
| **Begun more than one week postpartum** | | | | | | | |
| **Gomez-Rogers et al. 1967** (174) **Chile** | DMPA 500 (6-month injection) | 103 | 1–2 months | ≥ 10 months | 81 IUD users (see Table 10);<br>150 using no contraception;<br>92 using combined OCs (see Table 4).<br>Previous breast-feeding experience of each group. | Median duration of breast-feeding | Longer than for all control groups (SS) except IUD users, where duration similar. |
| **Gonzalez 1970** (175) **Mexico** | Chlormadinone acetate 0.5 | 50 | 5–40 days (later in 4 cases) | 9 months | Infant weight standards of Mexican Academy of Pediatrics | Infant weight gain | NSS |

NR = not reported    NSS = difference not statistically significant    SS = difference statistically significant

**Table 5 continued**

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Gupta et al. 1974, 1977** (197, 198) **India** | Norgestrel 0.05 | 30 | 6 weeks | 4.5 months | Nonhormonal group: 28 using female sterilization and 14 using other methods; 64 using combined OCs (see Table 4). (Pills allocated according to women's endocrine profiles.) Pretreatment experience. | Milk quantity by test weighing and breast pump; Number of supplementary feedings. | NSS |
| **Hefnawi et al. 1976** (223) **Egypt** | DMPA 300 (monthly injection)<br>Dihydroxyprogesterone acetophenide 150 (monthly injection) (Deladroxone)<br>Quingestanol acetate 0.3 | 25<br>25<br>25 | ≤1 month | 1 year | 238 diaphragm users and noncontraceptors evaluated in earlier study (221). Also studied: 25 users of another progestin-only OC (see Table 6). | Milk quantity by breast pump | Milk yield higher than for controls |
| **Huber et al. 1980** (240) **Bangladesh** | DMPA 150 (Depo-Provera) (3-month injection, except 450 mg for 6 months for ¼ of women initially) | 75 | 6–18 months (mean duration 7.0 months) | 4 months (mean duration of use 9.7 months) | Nonhormonal group: 76 using female sterilization and 27 using other methods or no contraception; 85 using combined OCs (see Table 4). | Weight for length; Mothers' impressions of breast milk quantity; Number of supplementary feedings per day; 24-hour breast milk quantity and caloric content for some. | Greater weight gain, smaller % reporting less milk among users than in nonhormonal group (SS). Other criteria: differences from nonhormonal group NSS. |
| **Kamal et al. 1969** (291) **Egypt** | Lynestrenol 0.5 | NR | 6–10 weeks | 5 months | Unreported number using IUD plus placebo or combined OCs (double-blind; see Tables 4 and 10). Previous breast-feeding experience. (120 participants in study.) | Age at supplementation and weaning; Women's impressions of breast size and fullness and of adequacy of milk supply; Milk quantity by test weighing and breast pump; Feed-to-weight adequacy; Infants' growth curves. | Results of various measures inconsistent but, overall, progestin-only ranked better than controls using IUD plus placebo. |
| **Pal et al. 1979** (427) **India** | Norethindrone acetate 0.4 (implant) | 25 | 6 weeks | 6 months | 25, contraceptive status not specified | Mothers' impressions of need for supplementary feeding | Fewer implant users felt supplementary food was needed (SS). |
| **Prema 1981** (454) **India** | DMPA 150 (Depo-Provera) (3-month injection)<br>NET EN 20 (monthly injection) | 22<br>51 | ≥3 months<br>≥6 months | 3 years | 1,917 noncontraceptors; 55 sterilized women; 68 IUD users (see Table 10); 102 users of combined OCs (see Table 3). Also, previous breast-feeding experience. | Duration of breast-feeding; Mothers' impressions of breast milk output during first month of contraceptive use. | Duration of breast-feeding similar for all groups and similar to previous experience. No abrupt decrease in milk output observed during first month of use. |

NR = not reported NSS = difference not statistically significant SS = difference statistically significant

## Table 6. Selected Studies of Progestin-Only Contraceptives That Found Adverse Impact on Breast-Feeding Performance

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Begun more than one week postpartum** | | | | | | | |
| **Hefnawi et al.**<br>**1976** (223)<br>**Egypt** | Chlormadinone acetate 0.5 | 25 | ≤1 month | 1 year | 238 diaphragm users and noncontraceptors evaluated in earlier study (221).<br>Also studied: 75 using other progestin-only contraceptives (see Table 5). | Milk quantity by breast pump | Milk yield lower than for controls and for other progestin-only formulations. |

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Note: Studies were included in Tables 7–8 if they involved at least 10 women in each group using hormonal contraceptives, included a comparison group, and specified the hormonal components of the contraceptive. Unless otherwise stated, contraceptive was administered orally. Levonorgestrel and *d*-norgestrel are the same compound, as are norethindrone and norethisterone.

**EE = ethinyl estradiol; ME = mestranol; DMPA = depot medroxyprogesterone acetate (Depo-Provera);**
**NET EN = norethindrone enanthate (Noristerat).**

**+ = significantly greater in cases than in controls**
**0 = no significant difference between cases and controls**
**– = significantly less in cases than in controls**

## Table 7. Selected Studies of the Effect of Combined Estrogen-Progestin or Estrogen-Only Contraceptives on Breast Milk Composition

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Effect on Milk Components | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Protein | Fat | Lactose |
| **Begun within one week postpartum** | | | | | | | | |
| **Toaff et al.**<br>**1969** (538)<br>**Israel** | EE 0.3 (estrogen only) | 66 | 1 day | 5 days | 46 using placebos.<br>Also studied: 63 using progestin-only OCs (see Table 8). (Pills randomly allocated, double-blind.) | + | 0 | 0 |
| **Begun at least one week postpartum** | | | | | | | | |
| **Abdel-Kader et al.**<br>**1969** (12)<br>**Egypt** | Lynestrenol 2.5 + ME 0.075 (Lyndiol 2.5) | 10 | 6–10 weeks | 16 weeks | 10 using IUD plus placebo; comparison with pretreatment milk.<br>Also studied: 100 using progestin-only contraceptives (see Table 8). | – | – | 0 |
| | Lynestrenol 1.0 + ME 0.1 (Lyndiol 1.0) | 10 | | | | – | – | 0 |
| | Dihydroxyprogesterone acetophenide 150 + estradiol enanthate 10 (monthly injection) (Deladroxate) | 10 | | | | – | – | 0 |
| **Barsivala & Virkar**<br>**1973** (43)<br>**India** | Norgestrel 0.5 + EE 0.05 (Ovral) | 16 | 1–9 months | 3 cycles | 8 using conventional methods; comparison with pretreatment milk.<br>Also studied: 15 using progestin-only contraceptives (see Table 8). | – | | 0 |
| **Gupta et al.**<br>**1974, 1977** (197, 198)<br>**India** | Norgestrel 0.5 + EE 0.05 (Primovlar) | 34 | 6 weeks | 3 months | 28 sterilized women and 14 using other nonhormonal methods; comparison with pretreatment milk.<br>Also studied: 30 using progestin-only contraception (see Table 8). (Pills allocated according to women's endocrine profiles.) | 0 | 0 | 0 |
| | Norethisterone acetate 1.0 + EE 0.05 (Minovlar) | 30 | | | | 0 | 0 | 0 |

**Table 7 continued**

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Effect on Milk Components | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Protein | Fat | Lactose |
| **Huber et al.**<br>**1980** (240)<br>**Bangladesh** | Norethindrone 1.0 + ME 0.05 (Noriday 1 + 50) | 40 | Mean about 7 months | 2 days | Nonhormonal group: 49 using female sterilization, condom, other nonhormonal methods, or no method.<br>Also studied: 30 using progestin-only contraceptives (see Table 8). | 0 | + | 0 |
| **Ramadan et al.**<br>**1972** (464)<br>**Egypt** | Chlormadinone acetate 3.0 + ME 0.1 (Ovosiston) | 20 | 2-4 months | 4 months | 20, contraception not specified | – | + | 0 |

### Table 8. Selected Studies of the Effect of Progestin-Only Contraceptives on Breast Milk Composition

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Effect on Milk Components | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Protein | Fat | Lactose |
| **Begun within one week postpartum** | | | | | | | | |
| **Badraoui et al.**<br>**1977** (631)<br>**Egypt** | DMPA 300 (monthly injection) | 25 | ≤2 hours | 1 year | 238 diaphragm users and noncontraceptors, evaluated in earlier study (13) | 0 | NR | NR |
| | Dihydroxyprogesterone acetophenide 150 (monthly injection) (Deladroxone) | 25 | | | | 0 | NR | NR |
| | Chlormadinone acetate 0.5 | 25 | | | | 0 | NR | NR |
| | Quingestanol acetate 0.3 | 25 | | | | 0 | NR | NR |
| **Koetsawang et al.**<br>**1972** (312)<br>**Thailand** | DMPA 150 (Depo-Provera) (3-month injection) | 30 | 2-4 days | 16 weeks | 25 users of nonhormonal contraception | 0 | 0 | 0 |
| **Toaff et al.**<br>**1969** (538)<br>**Israel** | 6-α-methyl-17-α-hydroxyprogesterone acetate 30 | 63 | 1 day | 5 days | 46 placebo users.<br>Also studied: 66 using estrogen-only OC (see Table 8).<br>(Pills randomly allocated, double-blind.) | 0 | 0 | 0 |
| **Begun at various times postpartum** | | | | | | | | |
| **Karim et al.**<br>**1971** (298)<br>**Egypt** | NET EN 200 (Noristerat) (3-month injection) | 68 | 7 days | 6 months | 100 using nonhormonal contraception | 0 | 0 | 0 |
| | | 57 | 6 weeks | | | 0 | 0 | 0 |
| | DMPA 150 (Depo-Provera) (3-month injection) | 51 | 7 days | | | 0 | 0 | 0 |
| | | 55 | 6 weeks | | | 0 | 0 | 0 |
| **Seth et al.**<br>**1977** (504)<br>**India** | Norethindrone acetate 40 (implant) | 23 | 6 days | 8 months | 15 using nonhormonal methods | 0 | NR | 0 |
| | | 12 | 6 weeks | | | 0 | NR | 0 |
| **Begun at least one week postpartum** | | | | | | | | |
| **Abdel-Kader et al.**<br>**1969** (12)<br>**Egypt** | Lynestrenol 0.5 | 10 | 6-10 weeks | 16 weeks | 10 using IUD plus placebo; comparison with pretreatment milk.<br>Also studied: 30 using combined OCs (see Table 7). | – | – | 0 |
| **Abdel Kader et al.**<br>**1976** (11)<br>**Egypt** | DMPA 300 (monthly injection) | 25 | ≤1 month | 1 year | 238 diaphragm users and noncontraceptors, evaluated in earlier study (13); comparison with pretreatment milk. | + | 0 | 0 |
| | Dihydroxyprogesterone acetophenide 150 (monthly injection) (Deladroxone) | 25 | | | | + | 0 | 0 |
| | Chlormadinone acetate 0.5 | 25 | | | | + | 0 | 0 |
| | Quingestanol acetate 0.3 | 25 | | | | 0 | 0 | 0 |

**Table 8 continued**

| Author, Date, Ref. No. & Place | Formulation of Hormonal Contraceptive (in mgs) | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Effect on Milk Components | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Protein | Fat | Lactose |
| **Barsivala & Virkar 1973** (43) **India** | Megestrol acetate 0.5 | 15 | 1–9 months | 3 cycles | 8 using barrier methods; comparison with pretreatment milk.<br>Also studied: 16 using combined OCs (see Table 7). | 0 | 0 | 0 |
| **Gupta et al. 1974, 1977** (197, 198) **India** | Norgestrel 0.05 + EE 0.95 (Primovlar) | 30 | 6 weeks | 3 months | 28 sterilized women and 14 using other nonhormonal methods; comparison with pretreatment milk.<br>Also studied: 64 using combined OCs (see Table 7). (Pills allocated according to user's endocrine profile.) | 0 | 0 | 0 |
| **Huber et al. 1980** (240) **Bangladesh** | DMPA (Depo-Provera) (injection, 150 mg every 3 months except 450 mg for first 6 months for ¼ of women) | 36 | Mean about 7 months | 2 days | 49 using female sterilization, other nonhormonal methods, or no contraception.<br>Also studied: 40 using combined OCs (see Table 7). | 0 | 0 | 0 |
| **Pal 1979** (427) **India** | Norethindrone acetate 40 (implant) | 25 | 6 weeks | 6 months | 25 using nonhormonal methods. | - | 0 | 0 |
| **Sammour et al. 1973** (490) **Egypt** | Chlormadinone acetate 0.5 | 20 | 2–4 months | 3 months | 20, contraception not specified. | - | 0 | 0 |

NR = not reported

## Table 9. Selected Studies of the Transmission of Hormonal Contraceptive Components in Breast Milk

| Author, Date, Ref. No. & Place | Hormone & Dose (in mgs)[a] | No. of Women | Initiation (Time Post-partum) | Length of Observation | Ratio of Concentrations in Plasma and in Milk | Mean Concentration in Milk (ng/ml) | Daily Dose to Infant (mg per 600 ml of Milk) | Daily Infant Dose as Proportion of Maternal Dose |
|---|---|---|---|---|---|---|---|---|
| Estrogens | | | | | | | | |
| **Nilsson et al. 1978** (412) **Sweden** | EE 0.05 (+ megestrol acetate 4.0) (Neo-Delpregnin) | 4 | 8 weeks | 1 day | Not detectable (ND) | ND (est. 0.015[b]) | ND (est. 0.01[b]) | ND (est. 0.0002[b]) |
| Progestins | | | | | | | | |
| **Koetsawang 1977** (311) **Thailand** | DMPA 150 (Depo-Provera) (injection) | 6 | 1–4 weeks | 12 weeks | 100:50[c] | < 2–16.5 | 0.0012–0.0099[d] | NR |
| **Nilsson et al. 1977** (411) **Sweden** | *d*-Norgestrel 0.03 (Follistrel) | 5 | 8 weeks | "As long as lactation lasted" | ND | ND | ND | ND |
| | *d*-Norgestrel 0.15 (+ EE 0.03) (Neovletta) | 5 | | | 100:15 | 0.25 | 0.00015 | 0.001 |
| | *d*-Norgestrel 0.25 (+ EE 0.05) (Follinett) | 5 | | | 100:15 | 0.50 | 0.00030 | 0.0012 |
| **Nilsson et al. 1977** (413) **Sweden** | Megestrol acetate 4.0 (+ EE 0.05) (Neo-Delpregnin) | 5 | 8 weeks | NR | 100:80 | 3.2 | 0.0019 | 0.0005 |
| **Saxena et al. 1977** (494) **UK** | DMPA 150 (Depo-Provera) (injection) | 7 | 1 week | ≤ 3 months | 100:85[f] | 0.5–2.3 | 0.00030–0.00138 | NR |
| | Norethisterone 0.35 (Micronor) | 5 | ≤ 1 month | 1 day | 100:18[e] | 0.37[e] | 0.00022[e] | 0.0006[e] |
| | *d*-Norgestrel 0.15 (+ EE 0.03) (Nordette) | 2 | ≤ 1 month | ≤ 20 days | 100:6 | 0.18[e] | 0.00011[e] | 0.0007[e] |

**Table 9 continued**

| Author, Date, Ref. No. & Place | Hormone & Dose (in mgs)$^{a}$ | No. of Women | Initiation (Time Post-partum) | Length of Observation | Ratio of Concentrations in Plasma and in Milk | Mean Concentration in Milk (ng/ml) | Daily Dose to Infant (mg per 600 ml of Milk) | Daily Infant Dose as Proportion of Maternal Dose |
|---|---|---|---|---|---|---|---|---|
| **Thomas et al. 1977** (533) **Thailand** | *d*-Norgestrel 0.03 | 3 | 2 weeks | 4–6 weeks | NR | 0.074$^{c}$ | 0.00044$^{c}$ | 0.001$^{c}$ |
| **Toddywalla et al. 1980** (540) **India** | Norethisterone acetate 1 (+ EE 0.03) | 4 | >6 months | 1 day | ~100:10 | 1.0$^{c}$ | 0.006$^{c}$ | 0.0006$^{c}$ |
| | *d*-Norgestrel 0.15 (+ EE 0.03) | 4 | >6 months | 1 day | ~100:10 | 0.25$^{c}$ | 0.00015$^{c}$ | 0.001$^{c}$ |
| | Norethisterone 0.035 | 4 | >3 months | 1 day | ~100:10 | 0.3$^{c}$ | 0.00018$^{c}$ | 0.0005$^{c}$ |
| | *d*-Norgestrel 0.05 | 4 | >3 months | 1 day | ~100:10 | 0.1 at 2 hours$^{c}$ (ND after 4 hours) | 0.00006$^{c}$ | 0.0012 at 2 hours$^{c}$ (<0.0006 after 4 hours$^{c}$) |
| | Norethisterone 25 (implant) | 4 | 6–12 weeks | up to 6 months postpartum | ~100:10 | 0.2 at 24 hours$^{c}$ (ND after 7 days) | 0.00012 at 24 hours$^{c}$ (est. <0.00003 after 7 days$^{c}$) | NR |
| | *d*-Norgestrel 25 (implant) | 4 | 6–12 weeks | | ~100:10 | 0.1 at <24 hours$^{c}$ (ND after 24 hours) | 0.00006 at 24 hours$^{c}$ (<0.00003 after 24 hours$^{c}$) | NR |

ND = not detectable
NR = not reported

Note: Includes only studies in which steroids were administered to fully breast-feeding women and then measured by radioimmunoassays. Does not include early studies with radioactively labeled steroids administered to lactating, but not breast-feeding, women.

[a] Administered orally unless otherwise specified.
[b] Based on women receiving 0.5 mgs ethinyl estradiol to suppress lactation, but calculated proportionally for daily contraceptive dose of 0.05 mg.
[c] Calculated or estimated from reported data.

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## Table 10. Selected Studies of Effect of Intrauterine Devices (IUDs) on Breast-Feeding

| Author, Date, Ref. No. & Place | Type of IUD | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Inserted within one week postpartum** | | | | | | | |
| **Hefnawi et al. 1975** (222) **Egypt** | Lippes Loop | 150 | Within 1 week | 1 year | 238 diaphragm users and noncontraceptors, evaluated in earlier study (221) | Milk quantity by breast pump | Not significantly different. (Milk composition also not significantly different.) |
| **Hingorani & Uma Bai 1970** (231) **India** | Lippes Loop | 185 | 3–7 days | 3 years | 106, contraception not specified | Duration of breast-feeding | Not significantly different |
| **Inserted more than one week postpartum** | | | | | | | |
| **Campodonico et al. 1978** (79) **Chile** | Lippes Loop, Copper T | 45 | 25–30 days | 3 months | 45 noncontraceptors; 60 using combined OCs (see Table 3). | Infant weight gain;<br>% still breast-feeding;<br>% still fully breast-feeding. | No significant differences in weight gain either for infants of all women or of fully breast-feeding women only.<br>No significant differences in % still fully breast-feeding.<br>Significantly higher % of IUD users stopped breast-feeding. |
| **Gomez-Rogers et al. 1967** (174) **Chile** | NR | 81 | 1–2 months | ≥10 months | 150 noncontraceptors;<br>195 using various hormonal contraceptives (see Tables 4 and 5).<br>Previous breast-feeding experience of each group | Median duration of breast-feeding | Significantly longer for IUD users than their previous experience, than for noncontraceptors, and than for 2 of 3 hormonal contraception groups. |

**Table 10 continued**

| Author, Date, Ref. No. & Place | Type of IUD | No. of Women | Initiation (Time Post-partum) | Length of Observation | Compared With: | Criteria Used to Measure Breast-Feeding | Results |
|---|---|---|---|---|---|---|---|
| **Guiloff et al. 1974** (195) **Chile** | Lippes Loop | 81 | 30 days | ≥ 10 months | Previous breast-feeding experience of all 385 participants, using various contraceptive methods, randomly assigned (see Tables 3, 4, and 5). | Median duration of breast-feeding | Significantly longer than combined previous experience. Also longer than current experience of all but one group of hormonal contraceptive users. |
| **Kamal et al. 1969** (291) **Egypt** | NR (plus oral placebo) | NR | 6–10 weeks | up to 32 weeks | Unreported number using hormonal contraceptives (double-blind) (see Tables 4 and 5). (120 participants in study.) | Age at supplementation and weaning;<br>Woman's impressions of breast size and fullness and of adequacy of milk supply;<br>Milk yield by test weighing and breast pump;<br>Feed-to-weight adequacy;<br>Infants' growth curves. | Overall, breast-feeding performance of IUD group was better than for 3 of the 4 hormonal contraceptive groups. Various measures gave inconsistent results, however. (No effect of IUD on milk composition (12).) |
| **Osteria 1976** (420) **Phillipines** | NR | 293 | Mean 1-2 months | 17 months | 260 noncontraceptors;<br>71 using hormonal contraceptives;<br>170 using other methods. | Duration of breast-feeding | Longer for IUD users than for noncontraceptors and users of hormonal contraceptors but not as long as for users of other methods. |
| **Prema 1981** (454) **India** | Copper T | 68 | NR | 3 years | 1,917 noncontraceptors;<br>55 sterilized women;<br>175 using hormonal contraceptives (see Tables 3 and 5).<br>Previous breast-feeding experience. | Duration of breast-feeding | Duration of breast-study groups and compared with previous experience. |

NR = not reported

Note: Studies were included in Table 10 if they involved at least 20 women in each group and used a comparison group. No studies show adverse clinical impacts of IUD use on breast-feeding.

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- Letters and numbers following entries refer first to the **Population Reports** series and then to page numbers within that series, e.g., B90 refers to Series B, Intrauterine Devices, page 90. Page number references apply to the English-language edition only. References to issue number 19 in Series J, Family Planning Programs, include two page numbers, for example, J23[367]. In the first printing, the pages were numbered J1-J29. When the issue was reprinted, page numbers were changed (J345-J374) so that the numbering is consistent with the J series as a whole. Thus, for each reference to Series J, Number 19, both old and new page numbers are shown, preceded by the notation *J-19*, for example: *J-19*: J23[367]. Pages in the Supplement to Series M, Number 4, are numbered 1-12; in this index they are preceded by the notation *M-4 Suppl.*:, for example, *M-4 Suppl.*: M2.

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FAMILY PLANNING PROGRAMS

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# Population and Birth Planning in the People's Republic of China

**Editors' Summary.** The People's Republic of China, with a population of about one billion people in 1981, is the first country in the world to embark on a deliberate and comprehensive policy to reach zero population growth by the year 2000 or as soon as possible thereafter. Stressing late marriage, universal use of contraception, and small families, China has reduced its birthrate from 34 per 1,000 in 1970 to 18 in 1979, according to government statistics. This is a decline unequalled by any other large developing country (see Figure 1, p. J-579).

By 1980, as a result of the recent campaign for one-child families, an estimated 51 percent of all births in China were first births, compared with 35 percent in Taiwan (1976) and 42 percent in the United States (1977). Moreover, by 1981 more than half of all couples with one child had pledged not to have another. By making a vigorous effort, Chinese leaders hope to counteract the demographic momentum generated in the 1950s and 1960s when family planning programs were not effectively carried out and birthrates generally exceeded 30 per 1,000.

The main features of the Chinese family planning program (called birth planning by the Chinese) are:

- strong commitment by national leadership,
- a highly organized social structure with strong political control, in which leaders at all levels are held responsible for birth planning activities, and families are rewarded or punished depending on their compliance with reproductive norms,
- continuing information, education, and motivation campaigns that utilize many different forms of persuasion,
- wide availability of a variety of fertility control methods.

### Leadership Commitment

Originally spurred by China's first census in 1953 and by a sample survey that revealed a population of almost 600 million growing at about 2 percent annually, Chinese leaders have for many years recognized the need to limit population growth. Although birth planning programs were interrupted in the late 1950s by the Great Leap Forward and again in the late 1960s by the Cultural Revolution, since 1971 birth planning has been given consistently high priority by the ruling Communist Party leadership, including Mao Zedong, Zhou Enlai, and their successors. The *wan xi shao* campaign begun by the national government in 1971 set "later, longer, fewer" as reproductive norms or goals for China. "Later" means later marriages, with the recommended age of marriage for women in the mid-20s and for men in the late 20s. "Longer" (or further apart) means longer intervals between births. Three or four years is recommended, to be achieved by regular use of contraception or abortion. "Fewer" means fewer children—in the early 1970s no more than two children per family in the cities and three in rural areas. These reproductive norms were vigorously promoted by party leaders, and in the mid-1970s the national government began to give instructions on what the natural increase rate of each province should be.

By the late 1970s Chinese leaders acknowledged that, because of the large number of people born during the 1960s and 1970s and now starting to marry, even a 2-child family would mean continuing population growth for at least half a century. Thus the one-child campaign was launched. By 1981, 57 percent of couples with only one child—11 million couples—had promised to have no more children and had received one-child certificates. The certificate entitles a couple to increased income, lower-cost health care, better housing, larger pensions, and eventually preferential treatment in schooling and employment for their only child. If a second child is born, the certificate holder has to repay any benefits. In addition, penalties are imposed on couples who have more than two children. The one-child campaign is a national norm

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**This issue of Population Reports was prepared by Pi-chao Chen, Ph.D. and Adrienne Kols, M.A.**, on the basis of published and unpublished materials, correspondence, and interviews. This is a revised and updated version of *Rural Health and Birth Planning in China*, by Pi-chao Chen, published by the International Fertility Research Program (IFRP) in 1981. The cooperation of IFRP is gratefully acknowledged. Comments and additional material are welcome.

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Phyllis T. Piotrow, Ph.D., Director; Walter W. Stender, Associate Director; Ward Rinehart, Editor.

applicable to all Chinese areas, but implementation and benefits depend on local resources.

The one-child campaign has been reinforced by an addition to the original slogan. To *wan xi shao* has been added *you*, so that *wan xi shao you* now means not only "later, longer, fewer" but also "better." The new slogan emphasizes the need for the one child in each family to have the best possible health care, education, and family life—in short, to be a perfect child. Thus, in an appeal to family pride, the quality of the new generation is stressed as a substitute for quantity. Couples also are exhorted to sacrifice their personal wish for more children in order to meet the national reproductive norms, which in turn are viewed as necessary to meet national economic development goals.

### Social and Political Organization

Much of the success of the birth planning program can be attributed to China's administrative and political structure and to the fact that birth planning is an integral part of the structure. The structure facilitates both vertical control of policy from the top and horizontal integration of services at the local level. Thus, birth planning information and services are provided or promoted by a multitude of institutions—government administrative units, Communist Party branches, health services units, and all the women's, labor, and other grassroots mass organizations. Many of these also have other functions. Basically, the central government sets provincial birth quotas and pays for contraceptive supplies and surgical procedures, while local units organize information and services, pay for local birth planning personnel, and ensure compliance with national instructions.

Mass information and persuasion campaigns are an important element in Chinese birth planning. Information and persuasion ranges from posters, mass media, hortatory speeches, locally prepared skits or comic dialogues, and the personal example of leaders to small group meetings or other occasions where peer pressure may be applied to "mobilize" couples to conform. Although national leaders seek voluntary acceptance of the reproductive norms, sometimes local officials use compulsion to meet birth quotas that might not otherwise be accepted. As one rural official said in an interview,

> Mobilization is different from persuasion. We persuade people to do this or that. But we mobilize the people to do this or that when we fail to persuade them in spite of our efforts. We hope they will understand later.

### Choice of Methods

Once couples are persuaded or mobilized, the Chinese program offers easy access at no cost to birth control methods that include oral contraceptives, IUDs, condoms, male and female sterilization, and abortion. Supplies and equipment are produced in China. In fact, China has pioneered in adapting many methods to local needs. The Chinese were among the first, for example, to develop low-dose oral contraceptives, to experiment with the paper pill, and to distribute a "visiting pill" for couples who see one another infrequently. IUDs are used by about half of all contraceptors, with almost 100 million reportedly inserted between 1971 and 1978; some are distinctive Chinese configurations such as the Canton Flower. About 30 percent of contracepting couples rely on sterilization. As the one-child campaign gains momentum, researchers are trying to develop methods of sterilization that are reversible in case a couple loses an only child. Induced abortion, normally by the vacuum aspiration method, which the Chinese pioneered for first trimester use, is also widespread and is encouraged when unplanned pregnancies occur.

Some facets of China's birth planning efforts are unique to the Chinese system and depend on a high degree of political control and community mobilization. Other aspects, however, would be appropriate in other countries—for example, providing a wide range of methods; combining family planning with a variety of other social services, including health; emphasizing part-time paramedical personnel working under professional supervision, like China's barefoot doctors; delivering contraceptive supplies door-to-door; using places of employment for education, services, and economic incentives; and sharing costs and responsibilities between local and national agencies.

It remains to be seen whether the Chinese birth planning program will succeed in stabilizing Chinese population early in the 21st century at a level of 1.2 billion, as Chinese leaders now hope. Since most Chinese couples want at least one son, those couples who have a daughter first (about half) may eventually try to have another child, thus exerting upward pressure on birthrates throughout the 1980s and 1990s. Nevertheless, the achievement of the People's Republic of China in cutting the birthrate in half in one decade and reaching a level below 20 per 1,000 is unprecedented among developing countries. Even if official records underestimate the number of births, the decline has been rapid and substantial. In an era when many developing countries will face rapidly growing populations along with a scarcity of other resources, China's demographic revolution has far-reaching economic and policy significance for the whole world.

**End of Editors' Summary.**

## BACKGROUND

As the population of the People's Republic of China (PRC) approaches and passes the one billion mark, the government appears more firmly committed to birth planning in 1982 than at any time in the past. The Chinese birth planning program is one of the oldest and strongest in the world, but until the last decade government implementation of birth planning was intermittent. The huge size of the Chinese population and the difficulties of feeding it have inevitably directed Chinese attention to birth control, but ideological debates over population theory and political upheavals have periodically interrupted birth planning efforts. Since the establishment of the communist regime in 1949, there have been four birth planning campaigns:

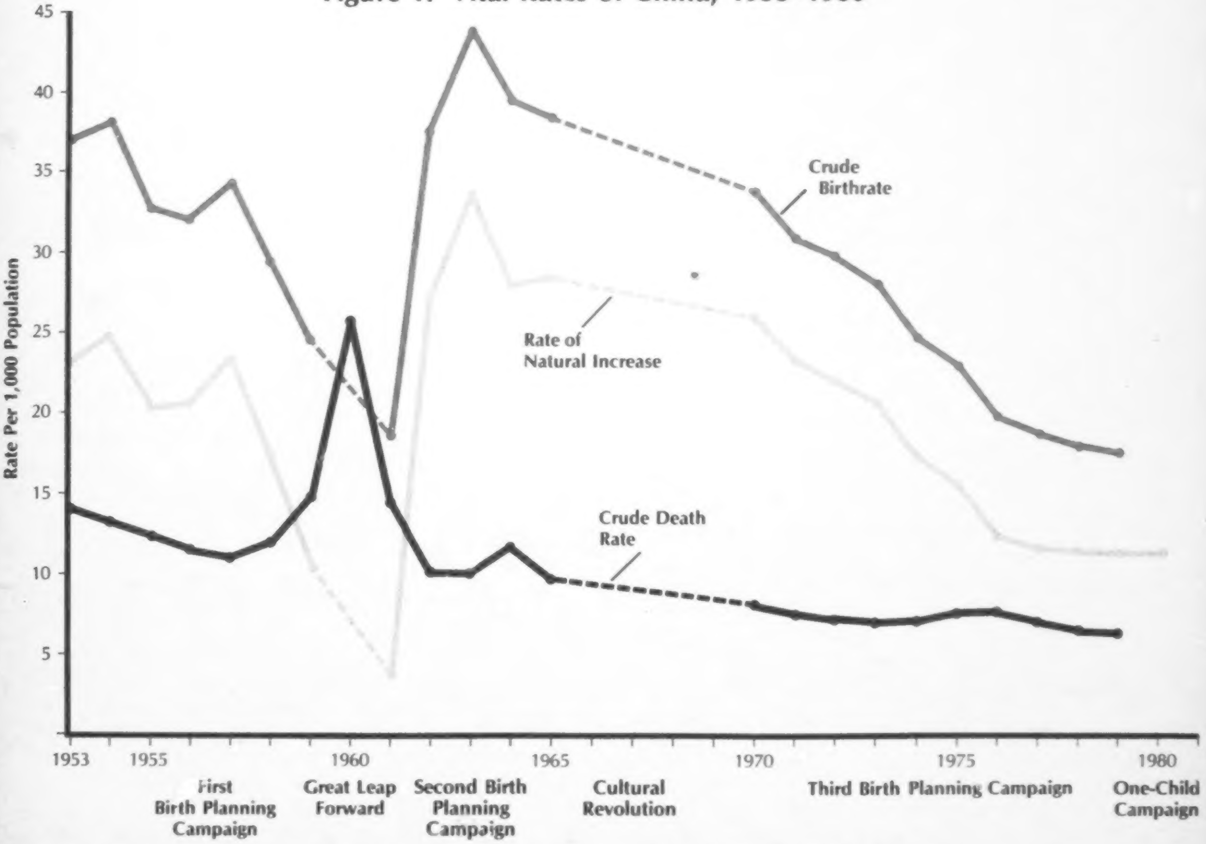
- The First Campaign, 1956–1958
- The Second Campaign, 1962–1966
- The Wan Xi Shao (Later, Longer, Fewer) Campaign, 1971–1979
- The One-Child Campaign, 1979–present.

The first two, much less effective campaigns were both followed by intervals of indifference or even active pronatalism, whereas the last two campaigns represent a decade of continuous and determined effort, initiated and pursued by the central government.

On the eve of the Chinese Communist Party's rise to power in 1949, Chairman Mao Zedong denied the existence of serious population problems. He explicitly rejected arguments that population growth would outstrip production and predicted that "revolution plus production" would solve the problem of feeding and employing China's people (314). In his words, "a country with vast land areas and plentiful material resources need not fear population growth" (110). In the years immediately after 1949 the Chinese communist leaders were also especially optimistic, since they had recently assumed power, stopped inflation, and held back the United States in Korea. Nevertheless, within a few years policies began to change. By August 1953 the Executive Council (the executive branch of the national government, later renamed the State Council) had approved a liberalized abortion regulation and directed the Ministry of Health to help the masses practice birth control (76, 123, 411).

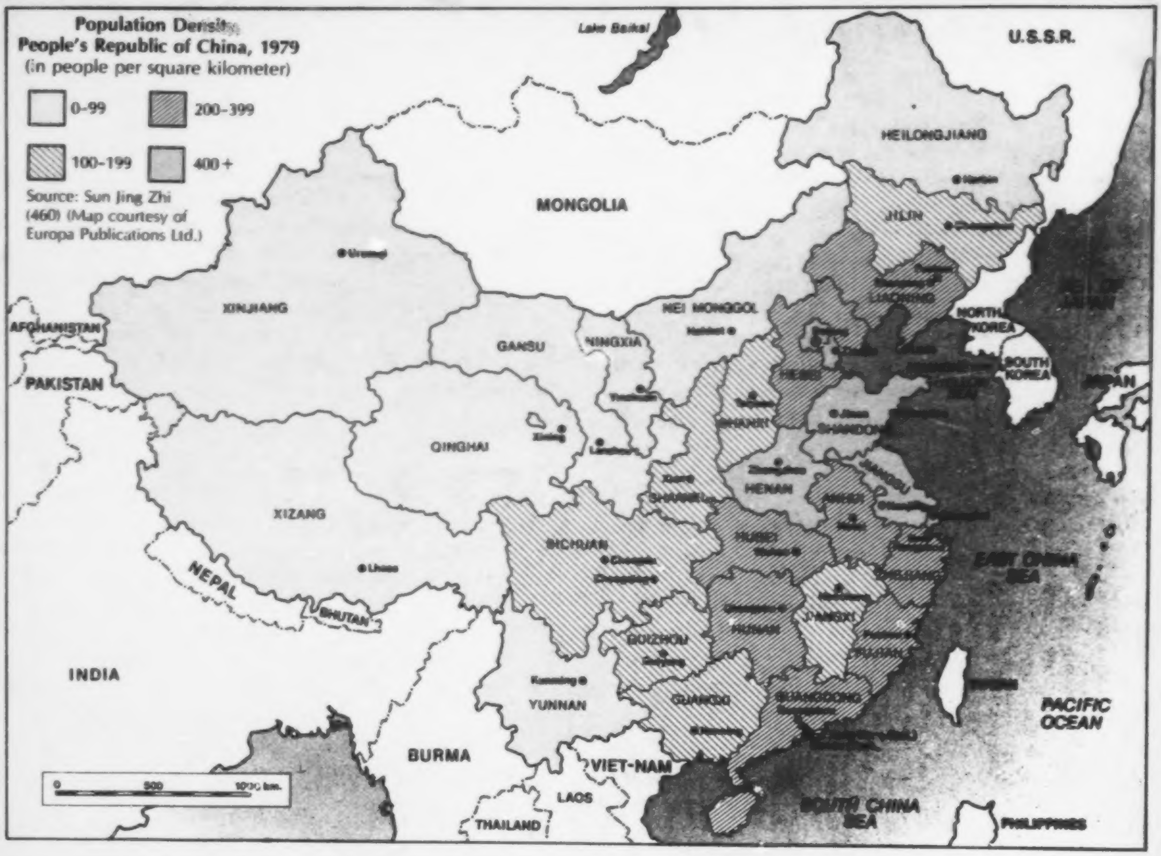
At first, since there were no accurate data on either population or natural resources, there was no basis for a rational population policy. The results of the first national census, conducted between the summer of 1953 and the spring of 1954, changed that. The census revealed a population of 582.3 million on mainland China as of June 30, 1953. A simultaneous sample survey of some rather unrepresentative areas disclosed a crude birthrate of 37 per 1,000 population, a crude death rate of 17 per 1,000, and, consequently, a natural increase rate of 20 per 1,000, or 2 percent per year (144).

Figure 1. Vital Rates of China, 1953–1980



Sources: 1953–56, 1958–59, 1961, 1963–65: Tian (383); 1957, 1962, 1968, 1970–79: Li (459); 1960: Sun (374); 1980: State Statistical Bureau (142).

**During the 1950s and 1960s birthrates fluctuated in response to birth planning efforts, political upheavals, and economic disruptions. During the 1970s the steady decline in birthrates can be attributed to the Third Birth Planning Campaign. Except for 1960 and 1966–69, for which no official figures are available, these data have been released by the State Statistical Bureau and are used by Chinese demographers.**


Population Density
People's Republic of China, 1979
(in people per square kilometer)
0-99
200-399
100-199
400+
Source: Sun Jing Zhi (460) (Map courtesy of Europa Publications Ltd.)
Lake Baikal
U.S.S.R.
HEILONGJIANG
Harbin
JILIN
Changchun
MONGOLIA
Urumqi
XINJIANG
AFGHANISTAN
PAKISTAN
NEI MONGGOL
Hohhot
LIAONING
NORTH KOREA
SOUTH KOREA
JAPAN
GANSU
NINGXIA
HEBEI
SHANXI
SHANDONG
QINGHAI
Xining
Lanzhou
HENAN
Zhengzhou
SHAANXI
JIANGSU
ANHUI
XIZANG
SICHUAN
Chengdu
Chongqing
HUBEI
Lhasa
NEPAL
BHUTAN
EAST CHINA SEA
JIANGXI
HUNAN
GUIZHOU
Guiyang
INDIA
Kunming
YUNNAN
GUANGXI
GUANGDONG
PACIFIC OCEAN
BURMA
VIET-NAM
LAOS
THAILAND
SOUTH CHINA SEA
PHILIPPINES
0
500
1000 km.

# POPULATION DISTRIBUTION IN CHINA

China's population is, as it always has been, concentrated along the eastern coast of the country. In the 1970s half of the one billion inhabitants of China lived in 15 percent of the country's land area located in the east. Population densities exceed 400 persons per square kilometer in six provinces and municipalities along the axis between the major cities of Beijing and Shanghai. By contrast, densities in the west and north are as low as 5 to 15 persons per square kilometer. Government-sponsored campaigns since 1949 such as "Face the Frontier Areas" and "Land Reclamation" have promoted migration from eastern cities to the west (386, 434). These movements have had strategic significance—by increasing the proportion of Han Chinese (the ethnic majority) near the Soviet border (102)—but their demographic impact has been negligible. Much of the sparsely populated area consists of mountains, virgin forest, desert, and other arid land that cannot support a dense population. Overall, two-thirds of China's land area is mountainous or semidesert; only 11 percent is cultivated (406).

The government has tried to curb migration from rural to urban areas. Peasants are prevented from moving to the cities (330), and urban youths have been relocated to the countryside (especially during the Cultural Revolution) (92, 121). Chinese policy seeks to prevent urban unemployment and to encourage progress in the agricultural sector as much as in the industrial sector (434). The result is that 80 percent or more of the population still lives in the countryside (24). Therefore the success of any Chinese birth planning effort depends on the rural areas.

The sparsely populated fringes of China are home to some 55 ethnic minority groups, who in 1978 numbered 55.82 million, or 5.6 percent of the PRC's population—down from 5.9 percent in 1953 (108). In the past these ethnic groups have been excused from Chinese birth planning campaigns. In fact, the government has tried to encourage their population growth by improving health care and the standard of living (361). In Qinghai and Yunnan, for instance, natural increase rates exceeded 19 per 1,000 in 1978—well over the national average of 12.

Despite the exemption, the government has always insisted that minorities have equal access to birth planning services, since some share the problems of unemployment and food shortages with the Han majority (116). More recently, Chinese population experts and some government officials have urged the extension of the full birth planning system to those minority groups with large populations, with little land, living in densely populated Han areas, or with an imbalance between economic development and population growth (51, 221, 236, 361, 384, 439). They argue that population policy should be determined by local demographic conditions, not ethnic background.

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These new figures spurred government action. In December 1954 the State Council set up a high-level committee to study birth control (124). Apparently a consensus was reached in a short time, since Premier Zhou Enlai officially endorsed birth control and opened the first birth planning campaign in a 1956 speech to the Eighth Party Congress (442). The government began to train birth control personnel and launched a large-scale publicity campaign. Mao himself spoke about the need to control population growth in order to facilitate the country's drive toward economic prosperity. Other party leaders soon echoed these sentiments (154).

This first birth planning campaign came to an end in 1958, when Mao introduced a new economic program, the Great Leap Forward, to decentralize industry and collectivize agriculture. During the Great Leap Forward production statistics were inflated, fostering a euphoric belief that Chinese production would forever outstrip consumption. Although no change in population policy was officially announced, Chinese publications strongly denounced "Malthusianism" and seriously proposed and discussed solutions for possible labor shortages (124). These attitudes contributed to the downfall of some Chinese social scientists who warned of the potential economic problems of continued rapid population growth (312). Chief among them was Ma Yinchu, who was removed from his position as President of Beijing University at that time and rehabilitated only in 1978 (154, 410). Ironically, during this period (1959–1961) the birthrate plummeted, not because of success in the birth planning program, which few units claimed, but rather because of widespread famine and the economic disruptions caused by the Great Leap Forward (see Figure 1, p. J-579).

As the Chinese economy began to recover from these policy blunders and from crop failures, in 1962 the government started a second birth planning campaign. The central government played a greater role in this campaign than in the first. The State Council set up a birth planning staff office (410). National symposia on the problems of birth planning, numerical targets for the growth rate, less restrictive abortion and sterilization laws, and measures promoting contraceptive use and late marriage quickly followed (154). Just as this birth planning campaign might have started to have an effect, the Cultural Revolution (1966–1968) disrupted the new program. Red Guard activities shut down factories and disrupted distribution networks, so that contraceptive supplies were cut off. Also, the Party's administrative control over the age at marriage broke down, so that people were free to marry early (449).

## MAO CHANGES HIS MIND

"The absurd theory that increases in food cannot catch up with increases in population, put forth by such western bourgeois economists as Malthus and company, has not only been refuted by Marxists in theory, but has also been overthrown in practice in the post-revolutionary Soviet Union and in the liberated China."

Mao Zedong, 1949 (314)

"Population [growth] must be controlled."

Mao Zedong, 1957 (301)

### The Third and Fourth Campaigns

A third birth planning campaign was launched after the restoration of order. A State Council Directive (Number 51), drafted and issued at the personal initiative of Zhou Enlai, formally announced the new policy in 1971:

> Birth planning is an important matter that Chairman Mao has advocated for many years, and demands serious attention by the leading comrades at various levels. Except for the thinly populated national minority areas and others, the leading comrades at each level must strengthen leadership, conduct penetrating propaganda and education, so that late marriage and birth planning become voluntary behavior on the part of the broad masses in cities and rural villages, and strive hard to accomplish outstanding results during the Fourth 5-Year Plan period 1971–75. (124)

Three reproductive norms, *wan xi shao,* guided the new birth planning program: later marriage, longer spacing between births, and fewer children (118, 120). Interviews with birth planning cadres (officials) throughout China in 1972 and 1973 made it clear that the provincial governments, acting on instructions from above, began to set ambitious, somewhat

**A female barefoot doctor treats a patient on the threshing floor. In China health and birth planning workers bring their services to the client at work or at home.** (Courtesy of Robert Parker)

**Physical exams and a survey of children's weights and heights are conducted at a rural daycare center. Health care has become more accessible in rural areas.** (Courtesy of Robert Parker) unrealistic numerical goals. The natural increase rate was to be reduced to 10 per 1,000 in the cities and 15 per 1,000 in the countryside before 1975 (124). In 1973 the national economic plan specified for the first time a numerical target for the intended population growth rate (411).

An internal struggle for power within the Chinese Communist Party was resolved with the death of Mao in 1976 and the subsequent arrest of the "Gang of Four," a group of radicals led by Mao's widow (406). The pragmatic veteran party officials who emerged as national leaders were even more strongly committed to birth planning than the previous leaders had been. The post-Mao leadership has given top priority to "the four modernizations"—agriculture, industry, defense, and science—as the PRC attempts to raise its per capita gross national product (GNP) from $250 (US) to $1,000—since scaled down to $800—by the year 2000. The leadership has publicly stated that the success of the four modernizations depends upon reaching zero population growth in the near future (262). In March 1978 this policy was incorporated into the Constitution; Article 53 of the revised Constitution reads: "The state advocates and encourages birth planning." Chairman Hua Guofeng immediately translated the constitutional provision into a numerical goal, urging that the natural increase rate be reduced to 10 per 1,000 throughout the country by 1980 (262).

In early 1979, apparently alarmed by internal population projections, the government shifted the emphasis of its birth planning efforts (411). This fourth birth planning campaign can be described as the one-child campaign. One internal projection indicated that, if the total fertility rate remained constant at the 1978 level of 2.3, the Chinese population would grow to 1.28 billion by the year 2000 (372). This projected population growth is rapid despite relatively low fertility because high crude birthrates in the 1960s and 1970s produced large cohorts that will swell the number of potential parents in the decades to come. As these cohorts marry, they will substantially raise the crude birthrate even if each couple has only two children.

In the face of this obstacle to zero population growth, the Chinese began the one-child campaign. In 1980 Party Chairman Hua Guofeng announced:

> If population growth is not controlled, there will be a dizzy peak [in the next two decades], making it virtually impossible for the economy and all our social institutions to cope. Upon careful study, the State Council deems it necessary to launch a crash program over the coming 20 to 30 years calling on each couple. . .to have a single child, so that the rate of population growth may be brought under control as soon as possible. Our aim is to strive to limit the population to a maximum of 1.2 billion by the end of the century. (261)

By preventing any births after the second child and encouraging the spread of the one-child family, the government hopes to lower the natural increase rate even though the absolute number and proportion of women of child-bearing age in the population will be increasing (260). Vice Premier Chen Muhua has pointed out that if 80 percent of urban couples and 50 percent of rural couples had only one child, a natural increase rate of 5 per 1,000 would be possible by 1985, and zero population growth would be achieved by 2000 or shortly thereafter (115). Chinese leaders recognize that this, like earlier numerical targets, will be difficult if not impossible to achieve. Nevertheless, such targets as 1.2 billion by the end of the century and the one-child family serve as a focus for their efforts.

**Figure 2. Vertical and Horizontal Political Organization in Rural China**

| Administrative Level | Population Size of Typical Unit | Executive Branch of Government | Chinese Communist Party Unit | Unit Responsible for Health Services Delivery | Birth Planning Unit |
|---|---|---|---|---|---|
| **Nation** | 900,000,000-1,000,000,000 | State Council | Politboro | Ministry of Health | State Birth Planning Commission and Birth Planning Staff Office of State Council |
| **Province (or Autonomous Region or Municipality)** | 2,000,000-90,000,000 | Provincial Government | Provincial Party Committee | Provincial Health Department (supervisory), Hospitals, Antiepidemic and MCH Stations | Provincial Birth Planning Committee and Provincial Birth Planning Staff Office |
| **County** | 400,000-600,000 | County Government | County Party Committee | County Health Bureau (supervisory), Hospital, Antiepidemic Station, MCH Station | County Birth Planning Committee and County Birth Planning Staff Office |
| **Commune** | 15,000-50,000 | Commune Management Committee | Commune Party Committee | Commune Health Center | Commune Birth Planning Committee and Full-Time Birth Planning Cadres |
| **Production Brigade** | 1,000-3,000 | Brigade Leadership Group | Brigade Party Branch | Cooperative Medical Station | Brigade Birth Planning Leading Group |
| **Production Team** | 250-800 | Team Leader | Party Cadres | Part-Time Health Aide | Part-time Birth Planning Workers |

**Each Chinese organizational unit is integrated vertically into a functional branch of government and horizontally into an administrative level. Thus a Commune Birth Planning Committee receives directions from the County, Provincial, and State Birth Planning Committees and from the Commune Management and Party Committees. It oversees production brigade and team birth planning workers.**

## ORGANIZATION

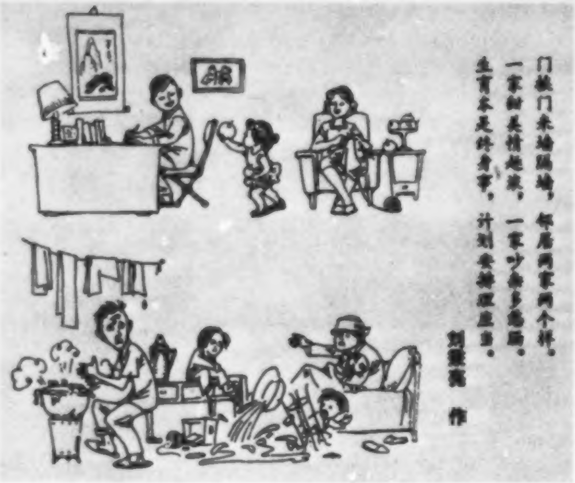
Much of the strength of the Chinese birth planning program is due to its unique organization, which can effectively transmit and enforce the policies of the central government at the local level. While a high degree of administrative control is found in most communist states, the PRC is the first nation to apply these mechanisms to achieve birth planning targets. Since 1971, throughout the third and fourth campaigns, birth planning in China has formed an integral part of the larger political and administrative framework that combines horizontal integration of all government functions at the local level with vertical control from the top. Birth planning units at each hierarchical level, working closely under Communist Party leaders, are in touch not only with the health establishment but also with mass organizations such as the Women's Federation. The health establishment delivers birth planning services, and the other groups persuade the people to participate. While policy and numerical targets are determined from above, the design and operation of birth planning programs are left to local discretion. Thus, local Party and government leaders influence the way in which general directives from higher levels are carried out.

Responsibility for financial support is shared. The central government pays for all contraceptive supplies and surgical services, but communities assume much of the financial responsibility for the program by supporting the birth planning personnel. Communities are also supposed to provide incentives to those undergoing birth planning operations (tubal ligation, vasectomy, IUD insertion, and abortion) and to those pledging to have only one child.

### Decentralized Policy Implementation

The PRC is divided into 29 provinces, autonomous regions, and provincial-level municipalities. Rural areas are further subdivided into counties, communes, production brigades, and production teams (see Figure 2). These lower-level administrative divisions—communes, production brigades, and production teams—are both geographic divisions and units of production. A comparable set of levels exists in the urban areas: districts, neighborhoods or wards, resident committees, and resident small groups. Groups organized around places of employment coexist with the residential divisions, so that urban workers may belong to factory committees in addition to residential committees.

These administrative levels can be visualized as a series of horizontal layers, cross-cut by vertical lines of power representing the functional branches of government. Figure 2 shows the four functional branches most relevant to population planning: executive, Party, health services, and birth planning. China's "multiple leadership" system controls the relationship between each of the units listed on the chart, including the birth planning offices. Each government body is subject to orders from: (1) other government bodies with a similar function at a higher administrative level (vertical leadership) and (2) the executive and Party organizations at the same administrative level (horizontal leadership). For example, the Commune Birth Planning Committee is simultaneously controlled by the Birth Planning Committees on the county, provincial, and national levels and by the Commune Management and Party Committees. Within this organizational network, the Chinese Communist Party (CCP) is paramount. It makes the major decisions and exercises leadership over *all* organized units in the country.


门挨门来墙隔墙，邻居两家两个样。
一家甜美情趣浓，一家吵闹多愁肠。
生育本是终身事，计划生育理应当。
作

**A cartoon promotes birth planning by contrasting two families:**

> **"Though they lived door by door,**
> **How different are these two families.**
> **One is sweet and lovely,**
> **The other is noisy and worrisome.**
> **Child-bearing is a life-long affair,**
> **Birth planning is certainly necessary."** (Courtesy of PIACT)

This organizational pattern is unusual. The government family planning organizations in most other developing countries operate either as part of a ministry of health or family planning or as a specially created unit. One advantage of the Chinese pattern is that it allows local governments a voice in the implementation of birth planning policies. In fact, policymakers on the national level expect the lower-level administrators to adapt national policies to local conditions. In the Chinese "party-state" major policy decisions are made by a few persons at the top of the CCP. Thus the possibility of making enormous mistakes is great. By couching major decisions and directives in general terms without specifying forms or procedures and by allowing local units to translate guidelines into actual programs, the Party Secretary and State Council seek to counterbalance this risk and give local units some freedom to adapt programs to local conditions.

Some local groups are more skillful than others in translating abstract principles of national policy into locally acceptable and effective programs (1, 33, 56, 61). The most skillful local innovators become models for the nation; they host on-the-spot conferences for cadres from other provinces. The national government expects and encourages other cadres to adapt the innovation and try it in their own areas. For example, Rudong, in Jiangsu province, was partly responsible for creating the birth quota system at the heart of the third birth planning campaign. A 1978 provincial discussion of birth planning work directed participants to imitate, catch up with, and overtake Rudong county (73). This kind of direct imitation assures that successful innovations in implementing policy directives are diffused.

Nevertheless, wide local variations occur in the degree of compliance with national policy. Chinese officials have repeatedly admitted to "uneven progress" in birth planning work across provinces and regions. They point to "strong Party leadership" as the reason for good performances, while "weak" leadership explains poor performances (56, 194, 202, 203, 219). For example, a reporter from Guangdong, analyzing the reasons for the province's rising natural increase rate, argued that leadership was the key factor. "Leading comrades" did not recognize the importance of birth planning, neglected the programs, and set a bad example for the province:

> Two years ago, a deputy secretary of the Boluo county party committee had a third child. Last year the daughter of a deputy secretary of the county CCP committee in charge of planned parenthood work also gave birth to a third child. The masses said, "If the top does not lead well, then the bottom gets confused; if the policies are not implemented correctly, the reason is to be found in the top." (188)

In Guizhou province, when Party and municipal officials were criticized for "laxity in enforcing birth control," more than 100 underwent sterilization to show that they had reformed their ways (192).

### The Health Care Delivery System

The general availability of health care in China is a recent phenomenon. Before the Cultural Revolution (1966–68), health benefits were far better in urban than in rural areas. Virtually all the state-funded hospitals were located in either the municipalities or the county seats, and the state-funded health insurance benefited only state employees. Most peasants had little or no access to any type of health care. On the eve of the Cultural Revolution, Mao issued a directive calling for a revolution in medical education and for more emphasis on serving rural areas. Mao's intervention, along with the dispersal of medical personnel throughout the country during the Cultural Revolution, provided the impetus to expand health care coverage to the rural population and to urban dwellers not previously covered by medical insurance (124). During the expansion the national government emphasized local initiative, community resources, and cooperative financing schemes in order to minimize the central government's financial contribution.

Prevention has consistently received the highest priority in the Chinese health system. Because the government has always explicitly linked improvements in health and increases in economic output, it has on occasion mobilized literally millions of laymen and placed them under the leadership of trained health professionals for environmental cleanups or antiepidemic campaigns (250, 351, 356). The birth planning programs have followed the same pattern. Rather than waiting for the people to come to the family planning professionals, the Chinese have trained large numbers of part-time aides to take contraception to the people. Every married woman is actively pressured, through home visits and group lectures, to join the birth planning movement.

Today's primary health care system in rural China is known as the "3-tier" system because it relies on three levels of the health care establishment:

- the brigade's cooperative medical station,
- the commune health center, and
- the county general hospital.

The 3-tier model has for the most part become fact in China. According to a recent report by the Minister of Health, each of the more than 2,000 counties has its own general hospital, antiepidemic station, and maternal and child health hospital; 55,000 communes, or about 90 percent, have their own health centers; and 700,000, or 90 percent, of the nation's production brigades have their own cooperative medical stations (344).

The Chinese recognize that it is impossible for a country with a vast and low-income population to have a fully qualified medical doctor in each town or village. Instead, they have tried to place one or more paramedical workers in each community, no matter how poor or remote, so that services are within walking distance of every citizen. This forms the lowest of the three levels. Altogether there are 1.46 million barefoot doctors—well-trained paramedical workers—or about one for every 600 rural peasants. Physicians and nurses are scarce, however (344) (see Table 1).

Every production team—a unit of 250 to 800 people—has a part-time health aide or maternal and child health worker who

**Table 1. Indicators of Health Care, People's Republic of China, 1979–1980**

**All China, 1979**

| | Number | Population per bed or worker |
|---|---|---|
| **Hospital beds** | 1,932,000 | 503 |
| **Medical workers**[a] | 2,642,000 | 368 |
| **College-graduated physicians** | 395,000 | 2,458 |
| **Middle-level physicians** | 435,000 | 2,232 |
| **Practitioners of traditional medicine** | 258,000 | 3,763 |
| **Nurses** | 421,000 | 2,306 |
| **Barefoot doctors** | 1,575,000 | 616 |

[a] These include pharmacists and antiepidemic workers as well as physicians and nurses.

Source: State Statistical Bureau (146)

**Rural China, Year-End 1980**

| | Number |
|---|---|
| **County hospitals** | 2,377 |
| **Beds** | 320,000 |
| **Antiepidemic stations** | 2,093 |
| **MCH stations** | 1,885 |
| **Health training schools**[b] | 1,165 |
| **Commune health centers** | 55,000 |
| **Beds** | 770,000 |
| **Cooperative medical stations** | 630,000 |
| **Barefoot doctors employed** | 1,460,000 |
| **Health aides & birth attendants serving at the team level** | 3,000,000 |

[b] These presumably are the training schools set up by the district and county hospitals to train and retrain the barefoot doctors.

Source: *Jian Kang Bao* (52)

farms most of the time. The aide's health activities, which include the distribution of contraceptives, are subsidized by the production team.

At the next administrative level, the production brigade, a cooperative medical service is financed by collecting dues from brigade members, selling medicinal herbs for profit, collecting fees from users of the service, and receiving allocations from the brigade's welfare fund (258, 259). Two to four barefoot doctors supervise preventive health measures, treat minor ailments, and provide contraceptive services. Complex medical problems are referred to the commune health center.

The commune health center is financed by county and provincial subsidies, user fees, and contributions. Physicians on its staff supervise the barefoot doctors, organize continuing in-service training for them, and treat complex cases.

Cases beyond the competence of commune health center doctors go to the county general hospital and the college-graduate physicians who staff them. The county general hospitals, antiepidemic stations, and MCH stations are funded entirely from the state's regular budget (258, 259). They provide technical support to and supervise the lower-level health care units.

The organization of medical services in urban areas is more complex and less uniform than in rural areas, but it follows the same basic pattern. At the heart of the health care service system are the residents' health stations, the urban counterparts of the rural brigade medical stations. Difficult cases are referred upward through several administrative levels to a comprehensive central hospital. In general, urbanites employed by large state enterprises have access to free health services where they work, while the rest, like the peasants, pay for medical care at the residents' health station.

The birth control delivery system has been built into the health care system. At least one barefoot doctor in every brigade medical center is female. Most of the female barefoot doctors are trained in contraceptive counseling and IUD insertions, and some are able to perform induced abortions by the vacuum aspiration method. With the assistance of part-time health aides and birth attendants, the female barefoot doctor provides prenatal and postpartum counseling, delivers babies, conducts contraceptive education, and keeps birth planning records. The female barefoot doctor is usually supervised by a women's work cadre, who manages and coordinates the birth planning work within the brigade. The local barefoot doctor, the part-time MCH worker or trained birth attendant, and the team-level health aide deliver contraceptives to households and accompany men and women to the commune health center to obtain birth planning operations—tubal ligation, vasectomy, IUD insertion, or abortion. Because the birth planning program relies on the 3-tier health system, birth control services are never far away in China.

### The Birth Planning Organization

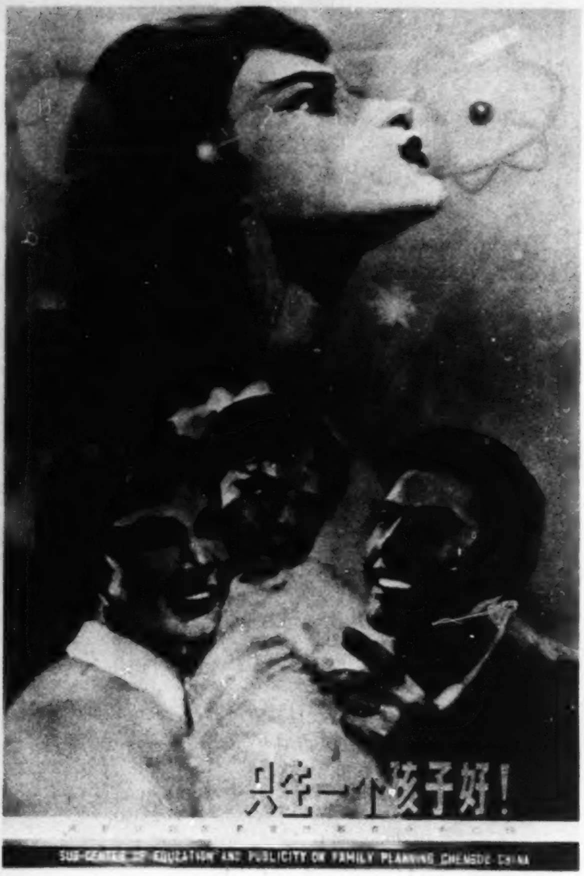
The birth planning organization of the PRC follows the same hierarchical pattern as the rest of the government. On the lowest level is the brigade's birth planning leadership group, which supervises the local barefoot doctors, the part-time MCH workers and birth attendants, and the team-level health aides who deliver contraceptive services. The group is also responsible for conducting the local information, education, and motivation activities within the brigade. Brigade groups are especially important because of the tremendous emphasis on the community basis of birth planning work. Whenever possible, birth planning workers are recruited locally; if they come from outside, they are expected to become permanent residents of the community they serve.

**The barefoot doctor makes her daily visit to the nursery of a rural production team. As families have fewer children, efforts to protect children's health are increasing.** (Courtesy of Robert Parker)

At the next larger unit of organization, the commune, there also is a birth planning leadership group, headed by the First Party Secretary of the commune, the commune's single most powerful member. The group includes members of all the relevant commune organizations: the commune Communist Party committee, the Commune Management Committee, the public security police station, the commune chapter of the Women's Federation, the Young Communist League, the militia, the local school system, the commune health center, and so on. This group supervises the implementation of the local birth planning program.

On the county level there is a birth planning office with a full-time staff. It supplies contraceptives to the communes and brigades, directs the information, education, and motivation activities, reimburses commune health centers for expenses generated by the four birth planning operations, and keeps records and statistics.

At the provincial level the Deputy Party Secretary of the provincial Party Committee or the vice-chairman of the provincial government presides over the provincial birth planning committee. Under this committee is the provincial birth planning staff office, which carries out the day-to-day operations of the provincial programs. Such staff offices have increased in size in


只生一个孩子好!
SUB-CENTER OF EDUCATION AND PUBLICITY ON FAMILY PLANNING CHENGDE CHINA

**Themes of women's emancipation and the modernization of China reinforce the birth planning message of this poster representing adoring parents. In English, the poster reads, "Honor to married couples with only one child," while the Chinese legend says, "How nice to have only one child!"** (Courtesy of John Chao)

recent years. The Guangdong Provincial Birth Planning Staff Office, for example, grew from a staff of 15 full-time workers in 1978 to 32 in 1981. The staff office is responsible for:

- allocating births among the units within its jurisdiction in order to meet the provincial annual birth plans and goals,
- supervising lower-level units in implementing the programs and realizing the goals,
- providing technical assistance, such as medical training programs, to lower-level units,
- organizing information, education, and motivation activities, including the printing of posters and the utilization of the mass media,
- identifying innovative, successful units within the province and diffusing their innovations by convening conferences at these units,
- calling annual provincial birth planning work conferences to set the next year's goals and commend advanced units,
- monitoring the program's progress, including the collection and tabulation of relevant statistics.

In addition, Guangdong recently established a birth planning science and research center with more than 40 full-time scientists, who devote most of their efforts to training medical workers in contraceptive techniques (134). Half of the staff office's budget in Guangdong goes for the purchase of contraceptive supplies and the reimbursement of lower-level units for the expenses of the four birth planning operations. Another 30 percent is spent on information, education, and motivation activities, including subsidies to lower-level units, while the remaining 20 percent pays for manpower training and research. In Guangdong the per capita expenditures of the provincial birth planning office increased from 12 cents (US) in 1977 to about 40 cents in 1980 (133, 134), a fairly typical figure.

Nationally, the Birth Planning Commission of the State Council is in charge of birth control. First created in 1956 as the Birth Planning Guidance Committee of the State Council (263), it was revived and reorganized as the Birth Planning Leading Group first in 1963 and then again in 1973 with Hua Guofeng as its head. Reorganized again in 1978, it was headed by Vice-Premier Chen Muhua. As part of an administrative change in March 1981, the group was named the State Birth (Family) Planning Commission, with Vice-Premier Chen Muhua continuing as its head (58, 207). This reorganization gives the new commission a permanent rather than an ad hoc status within the hierarchy of the State Council and enhances its authority. It is a supraministerial unit, drawing its members from a host of ministries, mass organizations, and related professional associations, in order to facilitate the coordination and execution of the birth planning program.

Under the State Birth Planning Commission is the Birth Planning Staff Office of the State Council, responsible for day-to-day coordination and supervision of birth planning programs throughout the country. This office sponsors an annual birth planning conference to which provincial and county birth planning staff offices send delegates. During the conference the national group transmits the latest policy directives to the lower units, receives reports from below, and rewards outstanding units (27). Specific plans for the following year are made final as lower- and upper-level units consult.

## THE THIRD CAMPAIGN: LATER, LONGER, FEWER

At the heart of China's birth planning efforts from 1971 through 1978 were the three new reproductive norms. PRC leaders asked all citizens to delay marriage, space the births of their children three or more years apart, and limit their families to two or three children. A quota system translated the reproductive norms into numerical targets and required each local group to plan its fertility behavior carefully, a process of community birth planning known as "birth planning by the masses." The government launched a massive campaign to persuade people to comply voluntarily and at the same time made use of social pressures, exerted by the small study groups to which most Chinese belong, to ensure compliance. Incentives, in the form of paid vacations for birth planning operations, supplemented the propaganda, and in some cases punitive or coercive measures were reportedly applied to those who refused to cooperate. For the first time, reducing fertility became a national priority, pursued consistently through a broad range of policies and programs.

### Reproductive Norms and Numerical Targets

The three reproductive norms were called *wan xi shao* in Chinese; this means "later, longer (further apart), fewer." "Later" meant later marriage. The minimum recommended ages for marriage differed between urban and rural areas as well as among regions. Generally, however, men and women were urged to postpone marriage to the ages of 28 and 25, respectively, in the cities and to the ages of 25 and 23 in rural areas. These recommended ages were higher than the legal minimum age of marriage, which was 20 for males and 18 for females until September 1980, when the minimum ages were raised to 22 and 20. According to the second norm, longer spacing between births, newlyweds could plan a first child right away, but subsequent births were to be spaced by 3-year intervals or longer in the countryside and at least 4-year intervals in the cities. The third norm, fewer children, originally was interpreted to mean two children in urban areas and three in the countryside (118, 120). In 1977 the concept was changed to mean two children in rural as well as urban areas.

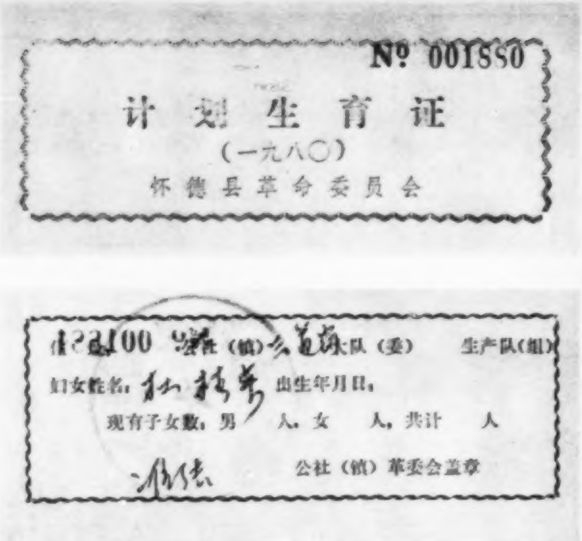
To enforce the reproductive norms and reduce the birthrate, in the mid-1970s the Chinese government began setting yearly targets for the natural increase rate in each province (172, 234). The targets established upper limits, based on such factors as level of socioeconomic development, previous performance, and ethnicity. For example, Qinghai province was assigned a maximum natural increase rate of 19.4 for 1978, a target which the province reached (220). Each province, after receiving the annual target established by the central government, allocated a birth quota to each of the counties under its jurisdiction. The process was repeated downward until it reached the production team or its urban equivalent (19). At this level, community birth planning took place. This determined which individuals were permitted to have children during the coming year. Taking into account those couples who planned to marry (such couples must report their plans to their employing or residential units months or even a year in advance and receive permission to marry), the birth planning unit assigned permission to have children to those couples who observed the three reproductive norms. Childless couples and newlyweds who observed the late marriage norm had first priority, followed by couples with one child age three or older. If the number of eligible couples was greater than the birth quota, some couples were forced to wait until the next year (124).

Some exceptions to the reproductive norms, although not always officially sanctioned, were allowed in practice. Early marriage could take place: if a young man had siblings to care for, but his parents were dead or ill, and he needed a wife to help; if a woman under age 23 was engaged to a young man about to join the military service, which would take him away from home for several years; and in many cities, where the age rule of 28 for men and 25 for women was relaxed to 26 for men and 24 for women.

## THE FUTURE OF CHINA

"If we control population development, we will obtain benefits. Not only will it reduce the burdens of the state, increase [capital] accumulations, and enable our country to become wealthy and powerful more quickly; it will also raise the scientific level of our country so that it will catch up with and surpass that of the [advanced countries] more quickly and accelerate the speed of our industrialization."

Premier Zhou Enlai, 1960s (297)



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计 划 生 育 证

（一九八〇）

怀德县革命委员会

公社（镇） 大队（委） 生产队（组）

妇女姓名： 出生年月日：

现有子女数：男 人，女 人，共计 人

公社（镇）革委会盖章

**This planned birth certificate entitles the woman named (Tu Xiuping) to have a child in the year 1980. The certificate must be shown at all prenatal examinations. Such certificates allow communities to control births strictly and meet assigned birth quotas.**

Community birth planning still takes place in China, but the norms governing the allocation of birth quotas have changed. Once the local birth planning committee has decided which couples are authorized to have a child, it issues each of them a planned birth card (see photo, this page). The card must be presented at prenatal obstetrical exams (389). Couples without these cards cannot have a child, even if they fit all the reproductive norms. All births not authorized by cards are defined as unplanned.

Each local birth planning unit submits its plan to the next higher administrative level. There the plans are combined and forwarded up another step in the hierarchy. Eventually the birth plans reach the provincial level. Adjustments may occur along the way, since in small units such as brigades the number of eligible parents varies widely from one year to the next. Normally, the plans are made final by May of the year preceding the year being planned.

Once a birth plan is approved, community members are expected to implement it. Couples who have been given permission to have a child may do so; others are expected to practice contraception or in cases of contraceptive failure to undergo abortions. Because events do not always occur as planned—eligible couples fail to conceive, an infant dies, a husband must be absent for a long time—periodic adjustments must be made. When a couple with permission fails to conceive and agrees to give up their birth for that year, the committee may grant another couple's repeated request for permission to have a child.

In some areas of China, eligible couples submit their own birth plans to the local birth planning group, which then draws up 3- to 5-year plans for the community. If the plan drawn up by a couple does not conform to the three reproductive norms, the group visits the couple to persuade them to change their plans. Since, for each couple that defies the norms, another eligible couple should postpone having a child, the eligible members of the community have a strong incentive to exert pressures on the defiant to comply. If there

11

are more eligible couples than available quotas, the qualified couples must meet and decide who must wait for another year (124, 309).

As couples become familiar with the three reproductive norms, the time-consuming group meetings that were first held to adjust individual plans become unnecessary. Instead, the community birth planning committee works out a 3- to 5-year birth plan for all its members based on the three norms and then notifies the couples concerned. Couples are expected to abide by the committee's decisions.

### Persuasion or Coercion?

The birth planning program in the PRC is officially committed to persuasion and education rather than coercion (301). Thus, a highly placed Chinese official informed visitors that, "Our birth planning work is carried out under the principle of providing guidance by the state with voluntarism by the masses" (327). A 1977 PRC textbook on population theory explains the meaning of "mass voluntarism" in more detail:

> It means that we hand the goal of the family planning policy and the population plan over to the masses, teach them to understand correctly the meaning of family planning, and arouse in them initiative and voluntarism. . . . They will choose family planning measures according to personal circumstances, turning family planning into a voluntary and conscious act. (304)

The PRC uses the same channels of information and authority to promote birth planning as it does to propagate other national policies. Slogans, posters, pamphlets, television and

## CHANGING CUSTOMS AND HABITS: A COMIC DIALOGUE

*In the PRC local community groups are encouraged to write and perform comic skits on birth planning for their own entertainment and education. For their humor, these skits rely on broad jokes about human nature. This excerpt is from a skit published in translation in its entirety in a collection of such materials edited by Leo Orleans (334). It tells the story of Mother K'ang, the deputy leader of a brigade birth planning group, and Lao Yao, the discontented mother of three daughters.*

**Mother K'ang:**
I was looking for you to discuss the matter of family planning.

**Lao Yao:**
Mother K'ang, our production brigade has already held a family planning meeting. You don't have to trouble yourself!

**MK:** Held a meeting? That is good. Then why haven't you been planning?

**LY:** This. . . Mother K'ang, to be very direct about it, if we have just one more child, then we will not want any more.

**MK:** I say you will still want more. You have three children that are girls. How can you not be thinking of having a change?

**LY:** Oh, you have this idea. No, we do not have this idea.

**MK:** From the personal names you have given your children, one can see that you still want a boy.

**LY:** How so?

**MK:** What is your oldest called?

**LY:** 'Yin-erh' ["lead to a son"].

**MK:** And the second?

**LY:** She is called 'Chao-nan' ["summon a male"].

**MK:** And the third?

**LY:** She is called 'Lai-ti' ["younger brother come"].

**MK:** Why did you give your children such names as these?

**LY:** It was for the sake of having a baby boy!

**MK:** You are speaking the truth.

**LY:** Without a baby boy, it will be hard to get things done in the future!

**MK:** But this kind of thinking doesn't make any sense! Chairman Mao said: "The times have changed; men and women are the same. The things which male comrades can do can also be done by the female comrades." Don't attach more importance to boys and less to girls. Now I ask you, in the countryside when we are raising cotton and planting rice, do we or do we not need planning?

**LY:** We do.

**MK:** When we are operating schools, do we or do we not need planning? When we are conscripting new soldiers, do we or do we not need planning? When we are developing the national economy, do we or do we not need planning?

**LY:** We do. We do. In everything we do.

**MK:** When the human race is developing childbirth, do we or do we not need planning?

**LY:** We do. Indeed we do.

**MK:** But you!

**LY:** I've always wanted to give birth to a baby boy, and so I've simply ignored planning. Mother K'ang, you have taught me a great lesson. Tomorrow I shall talk things over with my husband.

**MK:** That is good. Tomorrow I shall come to your home, and we can have a family meeting together. I shall participate as a delegate.

The next evening, which was windy and rainy, Mother K'ang hastened to her [Lao Yao's] home. She fell into the irrigation ditch and her entire body was drenched. But that contraceptive medicine she kept in her bosom was still well-protected, and she again started to propagandize the reasons for family planning to the "Lao Yao" couple. The couple then saw things clearly and determined to practice birth control. Then Mother K'ang took out the contraceptive medicine and placed it in the hands of Yin-erh's mother. From that time until now, they haven't had any children and have carried out family planning (255).

radio broadcasts, newspaper editorials, and public exhibits in the parks and museums all carry the birth planning message. Even songs, plays, and variety shows are used for motivational purposes (155).

Perhaps the most important component of this effort to change minds is participation in meetings and adult study groups during nonworking hours (155). When people fail to attend formal study groups, they are visited by birth planning delegations in their homes. The persuasive efforts in the meetings are direct and extremely personal.

Public discussion of private matters such as fertility control is socially accepted (98). During the third campaign birth planning workers appealed mostly to personal and familial goals, emphasizing how birth planning: (1) preserves the health of the married couple, (2) allows the parents and the state to make better provision for each child's education and upbringing, (3) leaves parents with more time and energy to devote to work and political study, and (4) liberates women in Chinese society (324). Couples who violate any of the three norms are confronted and rebuked by a combination of neighbors and Party cadres. Moreover, in birth planning, as in other national policies, the impact of official persuasion is strengthened by the lack of any voices or institutions within the country with authority to question or oppose government priorities.

In addition, people are offered positive incentives to use birth control. Since the early 1970s not only contraceptives, but also the four birth planning operations (vasectomy, tubectomy, IUD insertion, and induced abortion) have been offered free of charge at the place of the individual's choice. Men and women who undergo one of the contraceptive surgical procedures also are entitled to benefits in the form of paid leave from work (see Table 2). Extra work points may also be given for sterilization. (Work points are the equivalent of income in the agricultural communes, since they determine the individual's share of the collective's food and supplies.) Rural women can combine an operation with a trip to the city to visit friends and relatives. Normally people need permission from the local police to visit the city, and a birth planning operation is a legitimate reason to obtain permission. Units performing the operations are reimbursed either by one of the various medical insurance funds or by the local birth planning staff office (138).

Thus the birth planning campaign uses and officially encourages every available technique of persuasion including massive information campaigns, pressure by leaders and peers, and incentives. Yet it is unlikely that within a period of less than a decade so many Chinese couples have been convinced by these methods alone. When a Chinese peasant's traditional desire for many sons conflicts with the birth planning quotas set from above, the result may be either a failure to meet the quotas—which reflects badly on local cadres—or, alternatively, local cadres may resort to coercive measures to meet quotas that they know would not be voluntarily achieved (306, 432). Radio and newspaper reports rebuking cadres for heavy-handed measures suggest that they do occur. For example, some localities have dispatched "militant propaganda teams" to those households that did not practice birth control to "propagandize" and exercise control over their food, drinking water, and work points (189). In other areas, couples with male children were "mobilized" to undergo sterilization in order to fulfill sterilization quotas (209, 219). Local leaders also may urge or insist that women with unplanned pregnancies undergo abortions (23, 105).

## THE IMPORTANCE OF PLANNING

"To control population growth in a planned way is in the interest of planned development of the national economy, protection of mothers' and childrens' health, production of the broad masses, and their work and study. It must be grasped seriously and continuously."

Hua Guofeng,  
Premier (1976–80) and Chairman of the  
Chinese Communist Party (1976–81),  
1978 (262)

These measures, sometimes described as "mobilization," clearly go beyond persuasion. As a grassroots birth planning worker said in an interview:

> Mobilization is different from persuasion. We persuade people to do this or that. But we mobilize the people to do this or that when we fail to persuade them in spite of our efforts. We hope they will understand later. (96)

The central authorities have on occasion criticized local cadres who use "indiscriminate punishment" and "compulsory orders" in birth planning programs (231). Nevertheless, because of the high priority assigned to reducing population growth, the national government continues to issue directives

**Table 2. Benefits for Planned Birth Operations in Four Areas of the People's Republic of China**

| | **Taoyuan, Hunan Province 1978[a]** | **Luentsun Commune, Xian, Shaanxi Province 1978[a]** | **Nanning, Guangxi Autonomous Region 1978[a]** | **Yong-Jing County, Gansu Province 1979–80** |
|---|---|---|---|---|
| **Tubal ligation** | 21 days | 7–14 days | 10 days | 100 kg of grain, 200 *yuan*, 200 work points[b] |
| **Postpartum tubal ligation** | 30 days | 60 days | 7 days[c] | |
| **IUD insertion** | 7 days | 7 days | 3 days | |
| **IUD removal** | 7 days | 0 days | 2 days | |
| **Induced abortion** | 14 days | 14 days | 14 days | |

[a] Benefits listed are length of leave of absence from the field without losing work points. (The rural peasants do not receive wages.)

[b] For tubal ligation after 2 children; after 3 children, 50 kg of grain, 100 *yuan*, 100 work points. These are benefits provided by the communes. Some brigades additionally provide a goat and 2 kg of grain for tubal ligations after 2 children and half as much for tubal ligations after 3 or more children.

[c] Plus 56 days of maternity leave to which all women employed in government agencies or state-owned enterprises are entitled under the publicly funded medical care scheme and the labor insurance scheme

Sources: Taoyuan, Luentsun, Nanning: Chen (116)  
Yong-Jing: Ge & Li (244)

to meet numerical targets that sometimes lead to coercive measures at the local level.

## CONTRACEPTIVE METHODS AND THEIR USE

As a result of the vigorous efforts during the Third Campaign, contraceptive use in China is as extensive as in any developing country and approaches the levels of developed countries. The Chinese statistic closest to the contraceptive prevalence, or use, rate commonly used in international comparisons is the birth limitation rate. This rate is derived from program statistics rather than a survey at a single point in time. It counts as a user of birth planning any person who practiced birth control for any part of the year. Also, women who are naturally infertile are excluded from the denominator. Thus the birth limitation rate is higher than a prevalence rate. For China as a whole the birth limitation rate is estimated to be 70 percent—roughly equivalent to a prevalence rate of 60 percent (see Table 7, p. J-598). All of the most recently reported provincial and municipal birth limitation rates are above 70 percent. In Jiangsu and Hebei, two of the three provinces repeatedly singled out as having the best programs, the rates are 84 and 83 percent, respectively. By comparison, Hong Kong has a contraceptive prevalance rate of 79 percent (1979); Singapore, of 71 percent (1978); South Korea, of 49 percent (1978); and Taiwan, of 65.5 percent (1979) (326). The United States and other developed countries have rates of about 70 percent (169, 285).

In theory, all birth control methods are available to married couples. Since the early 1950s there have been no legal restrictions on any birth control method, and most remained available to some extent even when birth planning programs were in abeyance. In recent national meetings on birth control techniques, Chinese leaders have reiterated the importance of the "cafeteria" approach, in which all contraceptive methods are publicized and couples are allowed to choose among them (178, 215). In fact, the program has emphasized low-cost, highly effective methods—the IUD and sterilization. In recent years Chinese media have focused increasing attention on the four birth planning operations in an attempt to reach more demanding birth planning targets. The PRC is seeking to improve the quality and the supply of current drugs and devices and at the same time to develop new methods (178). Many small research projects, each often involving a single oral contraceptive formulation or IUD design, are underway at research institutes and medical schools throughout the country. Clinical studies require only provincial-level approval. Approval for general use and production quotas for contraceptives come from Beijing, however (339). All the contraceptives used in China are produced there, and self-reliance in the manufacture of contraceptives is an important concern.

### IUDs

In China, as in few other places, the IUD is the most widely used method of contraception. According to data compiled by the State Council Birth Planning Staff Office, probably as many as 50 percent of all contraceptive users rely on IUDs. Rural women are more likely to use IUDs than urban women. In Jiangsu province about 52 percent and in Guangdong province 55 percent of women use IUDs (see Table 3). By comparison, in the cities of Shanghai and Tianjin IUD users account for 25 and 37 percent, respectively, of contraceptive users. A total of 94 million IUDs were inserted between 1971 and 1978, as shown in Table 4, which summarizes statistics cited by a recent journal article and a government news release. There are no statistics on the number of reinsertions, dropouts, or switches to other methods. Even so, the number of IUDs in place in China alone undoubtedly exceeds the total for the rest of the world. Roughly 7 in every 10 IUD users is Chinese (340). Chinese women are most likely to choose an IUD after having one or two children, thus, in accordance with Chinese policy, completing their families (388).

A modified Ota ring made of stainless steel is the most common IUD, probably because it was the first type to be introduced to China and produced there (358). The ring has no tail and so can be removed only with a fine metal hook. It comes in 18 sizes, of which 4 are widely used. In 1979, 11 million of

**Table 3. Percentage of Married, Contracepting Women Using Specific Contraceptive Methods in the People's Republic of China and Selected Provinces and Municipalities, 1978–1980**

| Place & Year | Ref. No. | IUDs | Sterilization Female | Sterilization Male | Steroids | Others | Total |
|---|---|---|---|---|---|---|---|
| **China 1978** | 339 | 50 | —30— | | 8 | 12 | 100 |
| **Gansu province 1980** | 132 | 36.8 | 25.6 | 0.1 | 22.8 | 14.7 | 100 |
| **Guangdong province 1980** | 134 | 54.9 | 26.7 | 11.1 | 3.9 | 3.4 | 100 |
| **Jiangsu province 1978** | 137 | 52 | 32 | 7 | 7 | 3 | 100 |
| **Shanghai municipality 1978** | 140 | 25 | 40 | 7 | 17 | 11 | 100 |
| **Tianjin municipality 1978** | 309 | 37 | 16 | 0 | 26 | 21 | 100 |

**Table 4. Number of the Four Birth Planning Operations in the People's Republic of China, 1971–78**
(in thousands)

| Year | IUD Insertions | Sterilizations Female | Sterilizations Male | Induced Abortions | Total |
|---|---|---|---|---|---|
| **1971** | 6,173 | 1,745 | 1,224 | 3,910 | 13,052 |
| **1972** | 9,220 | 2,087 | 1,716 | 4,814 | 17,837 |
| **1973** | 13,950 | 2,956 | 1,933 | 5,110 | 23,949 |
| **1974** | 12,580 | 2,276 | 1,445 | 4,985 | 21,286 |
| **1975** | 16,744 | 3,260 | 2,653 | 5,084 | 27,741 |
| **1976** | 11,620 | 2,700 | 1,490 | 6,570 | 22,380 |
| **1977** | 12,974 | 2,776 | 2,616 | 5,229 | 23,595 |
| **1978*** | 10,739 | 2,530 | 763 | 5,528 | 19,560 |
| **1971–78** | 94,000 | 20,330 | 13,840 | 41,230 | 169,400 |

Sources: 1971-77: Zhang (437)
Cumulative 1971-78 total: *Jian Kang Bao* (39)
*1978: computed from the above two sources

these rings were produced. A study of 12,000 insertions reported a pregnancy rate of less than 2 percent and an expulsion rate of just over 5 percent at one year (339). The Tianjin, or *mahua* ("intertwined"), ring is a double coil of 0.23 mm stainless steel wire, which comes in seven sizes ranging from 18 to 24 mm in diameter (338, 339, 440). About 1.2 million are produced annually (339). (See photos, this page.)

Many of the IUDs used in China were designed there, and Chinese hospitals may display dozens of types (167). The Guangdong Provincial Maternal and Children's Hospital developed an IUD called the Canton Flower in 1962 (249). According to Chinese researchers, its three flexible plastic petals open and close as the uterus moves, making it less likely to dislodge (308). Another device, the Shanghai Copper V200, is made of silicone plastic surrounding a flexible wire frame approximately in the shape of the uterine cavity. Coiled copper wire, with a total surface area of 200 square mm, is applied to four locations on the device. Available in three sizes, the device is inserted or withdrawn by pulling down on nylon threads, tied at the top rather than the bottom of the device, until the two segments of the transverse arm overlap. In situ, the device assumes its original shape. Another Shanghai contribution, a variation of the T Cu200, is a plastic T with 200 square mm of copper coiled on the vertical stem. A Shanghai study with these devices found life-table pregnancy rates of 1.5 percent at one year and 4.8 percent at five years, explusion rates of 4.1 and 5.7 percent, medical removal rates of 9.2 and 22.5 percent, and overall continuation rates of 80.0 at one year and 29.1 percent at five years (438). Comparative studies of IUDs are now underway in China (339).

Several other new IUDs are now under development. Researchers in Hunan have combined the ring and T forms in a new IUD called the "Hunan Beetle" (see drawing, this page). This IUD, made of silastic impregnated with copper oxide over a wire core, has not yet been tested clinically. The developers hope it will be more difficult to dislodge and will exert less pressure on the uterine walls, thus reducing side effects (389). Chinese scientists also are working to develop IUDs that slowly release hormones in the manner of the progesterone-releasing IUD developed in the US (440).

### Sterilization

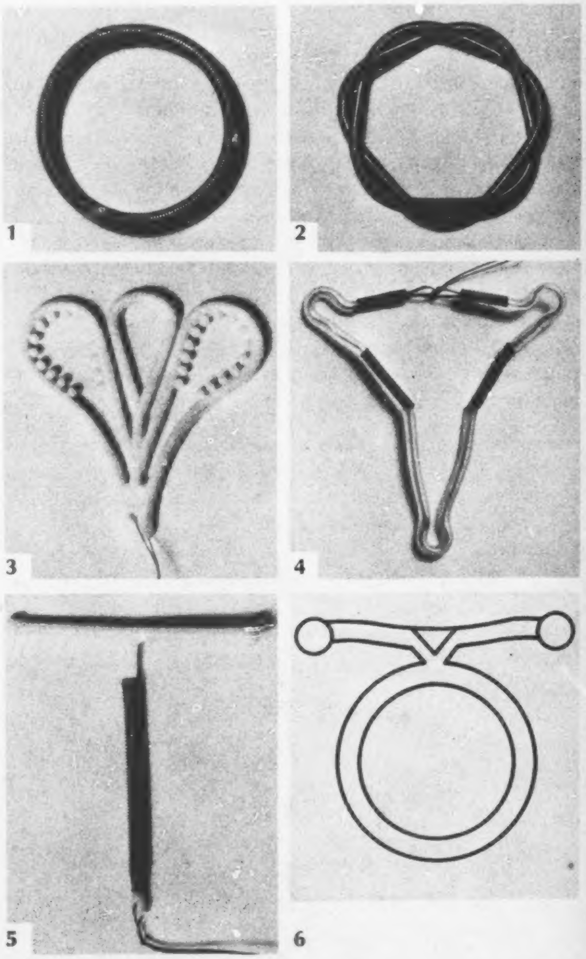
Sterilization is the second most widely used contraceptive method in China, relied upon by 30 percent of all contraceptors. According to Chinese data, a total of 20.3 million tubectomies and 13.8 million vasectomies were performed between 1971 and 1978, a ratio of 1.5 to 1 (see Table 4). In most places for which data are available, tubectomies outnumber vasectomies by a wide margin, at least two to one. The exception is Sichuan province, where vasectomy is widely used (339).

According to a study of four birth planning units conducted in 1979 by H. Yuan Tien, sterilized women are older. They married early, before strict birth planning programs began, and had had two, three, or four children before reaching their thirtieth birthdays. Men who chose vasectomies were in similar positions: they were fathers of three or four children before their wives reached age 30 or 35 (338). In some areas considerable pressure for sterilization has been applied to women with several children even though, in one case, some were already using IUDs. These pressures were brought to light by articles criticizing the cadres responsible (112, 432).

Since 1970 Chinese researchers have run clinical trials of a chemical, nonsurgical method of sterilization on almost 4,000 women. A mucilage mixture is inserted into the fallopian tubes with a catheter. The active ingredient, phenol, destroys epithelial tissue, causes inflammation, and blocks the tubes. In the most recent clinical series the rate of occlusion of both tubes was 93.5 percent. Of 2,487 women with both tubes blocked who were followed for two to seven years, only 2.6 percent became pregnant (348).

The Chinese use a phenol mixture in men by injecting it into the lumen of the vas deferens, creating a 1.5 cm block. This procedure takes less than 10 minutes, compared with 10 to 15 minutes for conventional vasectomy, and is reportedly safer, simpler, and more reliable than vasectomy. By comparison with vasectomy, it is said to produce less hematoma, infection, and damage to surrounding tissue. As of August 1979 more than 50,000 men had been sterilized by this method, with 91 percent effectiveness reported (40).

Women with only one child need a safe, long-term birth control method that is reversible, so that they can have a second child if the first dies or is disabled. Chinese researchers, therefore, now have a special interest in reversible sterilization to increase the appeal of the procedure. In Beijing researchers



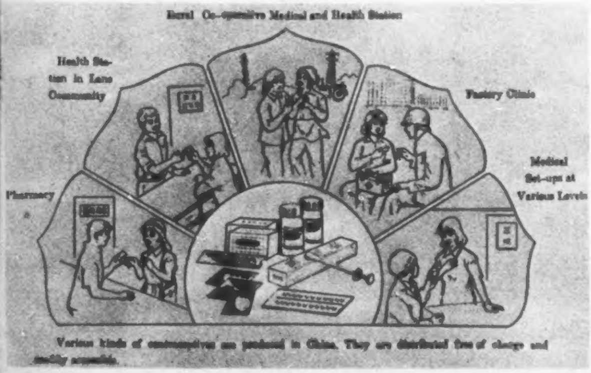
**Half of all contraceptive users in the People's Republic of China rely on IUDs. The most widely used is the stainless steel ring (1). The *mahua* ring is also used (2). Others in limited use or under study are the Canton Flower (3), the Shanghai Cu V200 (4), the Shanghai T Cu200 (5), and the Hunan Beetle, shown in silhouette drawing (6).** (1–5 courtesy of PIACT, 6 courtesy of Tien Kai-Hui) are experimenting with clips of titanium and silicone rubber, while in Hunan they have begun clinical trials with two types of clips, one of silver and the other of plastic (161, 389). As with other clips (251), some surgical reanastomosis is necessary when these clips are removed, but the reversal procedure is easier than with more conventional methods of sterilization.

### Steroidal Contraceptives

Several varieties of oral contraceptives are available in the PRC. The pill now most widely used is a combination of 0.3 mg *dl*-norgestrel and 0.03 mg ethinyl estradiol. Other pills widely used are the low-dose Oral Pill No. 1, a combination of 0.625 mg norethindrone and 0.035 mg ethinyl estradiol, and Oral Pill No. 2, consisting of 1.0 mg megestrol acetate and 0.035 mg ethinyl estradiol (339). All these pills are taken daily for 22 days a cycle. In addition, a visiting pill, a once-a-month pill, and monthly injections are used to a limited extent. Tien's study of four birth planning units found that pill users are characterized by their youth, extremely low parity, and urban residence. Women tend to use the pill to delay a second or third birth (388), and, more recently, also to delay first births.

Although hormonal contraceptives are supposed to be universally available, in practice they are in limited supply in rural areas. In two of China's largest cities, Shanghai and Tianjin, 17 and 26 percent of contraceptive users relied on steroidal contraceptives in 1978. In contrast, steroids account for only 7 and 4 percent in the provinces of Jiangsu and Guangdong. Gansu, an economically backward province in the northwest, is an exception: pill users make up a surprising 23 percent of currently contracepting women (see Table 3). For China as a whole steroids reportedly account for 8 to 10 percent of all contraceptive use (339, 352). One reason for relatively slight use of steroidal contraceptives is Chinese concern about workers' exposure to steroids in the manufacturing plants, which lack the sophisticated ventilation systems and other safeguards needed. As a result, although production equipment could yield an estimated 260 million cycles, production is held down to reduce workers' exposure. About 120 million cycles were produced in 1979 (339).

Chinese research has produced several variants on the pill since the early 1960s—the low-dose pill, the drip pill, the paper pill, and the "visiting pill" (339). Initially, in the early 1960s, the Chinese pill contained a combination of 2.5 mg norethindrone and 0.5 mg ethinyl estradiol. Thus it was comparable in strength to North American and European pills of the time. By 1965, however, the Chinese began clinical testing of a pill with half as much progestin and, two years later, one quarter as much. This quarter-dose version (0.625 mg norethindrone and 0.035 mg ethinyl estradiol) is now the Oral Pill No. 1. Before 1970 researchers in Shanghai experimented with a pill containing one-eighth of the original dose, but side effects, especially irregular bleeding, proved too great (166).


Rural Co-operative Medical and Health Station
Health Station in Lane Community
Factory Clinic
Medical Set-ups at Various Levels
Pharmacy
Various kinds of contraceptives are produced in China. They are distributed free of charge and readily accessible.

**A strength of the Chinese birth planning program is ready accessibility of contraceptives. Couples can receive their choice of contraceptives free at various outlets.** (Courtesy of John Chao)

There are three reasons that the Chinese pioneered the use of low-dose pills. First, they believed that low doses would minimize side effects and complications, especially in the liver, where they feared complications would be found. This would reduce the need for close medical follow-up, which the Chinese could not afford. Second, low doses utilize the available steroid raw material as efficiently as possible (166). Third, they reduce workers' exposure to steroids (339).

The drip pill, manufactured by a unique method, has been developed in China, also to minimize workers' exposure to steroids. Conventional tablets are made from a dusty powder that can be inhaled, but the drip pill is made from steroids in solution. The solution drips through a perforated plate into a column of liquid paraffin. The steroid drops settle to the bottom of the paraffin, are removed, coated with sugar, and packaged. The method seems to produce uniform doses, and the pills are much smaller than conventional tablets with the same steroid content. About 30 million cycles of the drip pill are produced annually, using the *dl*-norgestrel and ethinyl estradiol combination, compared with about 37 million cycles of the same formulation in tablet form (339).

The paper pill, although it has been widely publicized outside the PRC, is produced only in limited quantity—4 to 5 million cycles in 1979 (339). First developed in Shanghai in the early 1970s, this oral contraceptive uses the same steroids as Oral Pills No. 1 and No. 2. It is manufactured by dipping an edible paper (carboxymethyl cellulose) into a steroid solution. After the paper is treated, it is perforated into small squares, each of which constitutes a daily dose. A woman takes the paper pill on the same schedule as the tablet form (338). In China the paper pill has four advantages over the conventional tablets: (1) the lighter and smaller paper pill is easier to store and ship; (2) both the raw materials of the pill and the packaging are cheaper; (3) workers are less exposed to steroids during the manufacturing process; and (4) the paper pill's simpler technology requires fewer people, less equipment, and less space (166). Problems with supply of its special paper have kept production low, however.

Another kind of oral contraceptive, the "visiting pill," is designed for the vacation reunions, often a month long, of Chinese couples separated for the rest of the year by job assignments. Researchers developed these postcoital pills to reduce the amount of steroid ingested by such women, although it may be taken regularly for up to six weeks and thus amount to a relatively high dose for a short period (166, 243, 338, 397). Women take one pill after the initial coitus, a second the following morning, and then one pill after each subsequent coitus. Anordrin, also called Pill No. 53, is the most widely used of several visiting pills. It contains 7.5 mg of the synthetic steroid anorethidrin diproprionate, which, according to animal experiments, has some estrogenic activity (277). A series of clinical tests in China of Anordrin administered at different times in the menstrual cycle has shown that the drug may decrease plasma progesterone levels, shorten the luteal phase of the menstrual cycle, affect endometrial morphology, inhibit

**A barefoot doctor and a commune health worker start on a round of home visits in Shanghai county. The PRC relies on these part-time medical workers, among others, to deliver contraceptive supplies as well as to treat illnesses.** (Courtesy of Robert Parker)

ovulation, and suppress the development of Graafian follicles and the corpus luteum in the ovary (247, 256, 257). During 1979 the PRC produced about 25 million tablets of Anordrin, suggesting that it accounts for no more than one percent of all contraceptive use (338).

Two types of once-a-month contraceptive are available in China—a pill and an injection. The monthly pill, consisting of 12 mg norgestrel and 2 mg quinestrol, is manufactured in Beijing. About 3 million tablets were produced in 1979. In the first cycle of use one tablet is taken on the fifth day after the start of menses and another tablet is taken on the 25th day. Subsequently, one tablet is taken in each cycle (339). Other once-a-month oral formulations are under study in China (91). The injection consists of 250 mg 17-hydroxyprogesterone caproate and 5 mg estradiol valerate. Production is currently limited to 10 million doses a year (339).

### Condoms

Perhaps about 6 percent of contraceptive use in China involves condoms. In 1979 some 710 million pieces were manufactured in China, but probably not all were used. Condoms are available in three sizes. The manufacturers think that the opaque color, lack of lubrication, and uneven thickness of the condom limits acceptability. They are looking forward to obtaining new equipment, under an agreement with the UN Fund for Population Activities, that will produce, test, and package transparent, lubricated condoms (281, 339).

### Abortion

In China induced abortion is readily available and is granted to a woman free of charge upon request, without requiring her husband's consent (263). Some female barefoot doctors serving in remote brigades have been trained in the vacuum aspiration procedure for terminating early pregnancy. For abortions after the first trimester, patients are referred to commune health centers or the county hospital.

The official position on induced abortion is that, although safe, it should not be used as a method of contraception but should be used in the event of contraceptive failure. Despite the official position, induced abortions are common. Table 5 summarizes the statistics for the whole of China. The abortion rate per 1,000 women age 15 to 44 remained relatively constant during the 1970s, at an average level of 26. Due to the falling birthrate, however, the abortion ratio per 1,000 live births increased steadily during the same period, from 128 in 1971 to 318 in 1978. The Chinese abortion rate and ratio of 26 and 318, respectively, are similar to or lower than those of Singapore and the United States. In Singapore in 1976 the abortion rate was 27.4 and the abortion ratio was 371. For the US in 1977 the equivalent figures were 25.8 and 385 (390). The rate for China may not be strictly comparable to the others, however. Relatively few Chinese women marry before age 22, and if there is relatively little premarital sexual activity, as Chinese sources often contend, more of the women considered in the Chinese rate are not exposed to the risk of pregnancy. Abortions are performed in the second trimester about as often as in developed countries. In Beijing in 1978, 9.13 percent of the 93,879 induced abortions were performed during the second trimester (342). This compares with figures of 6.4 percent for Sweden (1976), 9.7 percent for the US (1976), and 14.1 percent for England and Wales (1975) (390).

In China's major cities the incidence of induced abortion has been considerably higher than the national average. In Beijing and Tianjin in 1978, there were 940 and 651 induced abortions, respectively, per 1,000 live births (309, 342). The rural counties of Xinhui (Guangdong province) and Taoyuan (Hunan province) had far lower abortion ratios, 288 and 279, respectively, in 1979. When asked why more of the pregnancies in urban areas end in abortion, Chinese birth planning administrators and doctors gave several explanations. One reason is a real difference in behavior: people who live in cities are more

**Table 5. Number of Abortions, Abortion Rates, and Abortion Ratios in the People's Republic of China, 1971–78**

| Year | Number of Abortions[a] | Abortion Rate (per 1,000 Women Age 15–44[b]) | Abortion Ratio (per 1,000 Live Births[c]) |
|---|---|---|---|
| **1971** | 3,910,000 | 21.6 | 128 |
| **1972** | 4,814,000 | 25.8 | 193 |
| **1973** | 5,110,000 | 26.6 | 209 |
| **1974** | 4,985,000 | 25.1 | 212 |
| **1975** | 5,064,000 | 24.9 | 242 |
| **1976** | 6,570,000 | 31.2 | 361 |
| **1977** | 5,229,000 | 24.2 | 323 |
| **1978** | 5,528,000 | 24.8 | 318 |

[a] Source: Zhang (437)

[b] Numbers of women age 15–44 are derived from computer simulation of the population growth of China, 1953–78 (120).

[c] Source for number of live births used in computation: Wang (410)

## A STRATEGIC QUESTION

"We must squarely face the fact that rapid population increase obstructs economic development. Under current conditions in our country, the question of whether or not to control population increase is not merely a question of whether to have fewer or more babies; it is a strategic question that bears on the development of our country's productive force, on the realization of the four modernizations, and on the transition from socialist construction to communism."

Chen Muhua,
Vice-Premier and Head of the
State Birth Planning Commission,
1979 (115)

strongly motivated to limit their family size and readier to resort to induced abortion to terminate unplanned pregnancies than are rural inhabitants. Other factors, however, make the difference seem larger than it actually is. Many induced abortions performed in the city hospitals are cases referred from the countryside. Some rural women prefer to have the procedure done in city hospitals because they believe they will receive better care and because the trip allows them to visit relatives and friends who live in the city. Also, late terminations are done in the major hospitals in cities, regardless of where the woman lives. For these reasons, the statistics exaggerate urban-rural differences. Contraceptive use rates are similar in cities and rural areas, however, so the higher urban abortion rate probably does account in part for the much lower crude birthrate in cities.

Until recently Chinese birth planning administrators either were silent on the subjects of premarital sex and pregnancy or dismissed them as inconsequential. In Shanghai, however, most of the teenage girls in a reformatory were there for having "affairs" with boys (354). Recent data show that, in a teaching hospital in Tianjin, termination of pregnancies in unwed women accounted for 9.3, 14.2, and 15.6 percent of all induced abortions performed there in 1977, 1978, and 1979, respectively (309). Also, unmarried women may go to illegal abortionists to avoid the jokes and reprimands of the hospital staff and social peers (171).

The Chinese were early advocates of the vacuum aspiration method of abortion and carried out the first clinical evaluations of the method in the late 1950s (392, 425). They have designed vacuum equipment to meet the specific needs of rural practitioners without well-equipped clinics. A 1964 innovation was the vacuum bottle, a design based on a traditional Chinese cupping therapy. The technician produced a vacuum by throwing a lighted match into a bottle containing alcohol and quickly corking the bottle (424). Later the Chinese designed a foot-operated pump, small in size, light in weight, and of simple construction, for barefoot doctors and mobile medical teams (338). This portable pump has facilitated abortion outside hospitals and in rural areas.

Chinese researchers, pursuing the nation's traditional interest in herbal medicine, have discovered a number of indigenous plants with abortifacient properties. Following a suggestion in a 16th-century compendium of *materia medica,* the Shanghai Institute of Experimental Biology in 1973 began efficacy and safety studies on trichosanthin, a derivative from the root of *Trichosanthes kirilowii,* a member of the Cucurbitacea, or gourd, family. Although demonstrated effective in inducing both first and second trimester abortion when given by intramuscular injection (62, 160), its use as an abortifacient was discontinued in some areas in 1979 because of side-effects such as nausea, headaches, and fever. Laboratory and clinical tests are continuing, however (161, 282). Another abortion method, using *yuanhua,* a member of the Thymelaeaceae, has been under clinical evaluation in Shanghai (360). Its active ingredient, yuanhuasine, may cause inflammatory reactions in the placenta and subsequent tissue necrosis (440). Researchers at the Beijing Medical College have tested the herbal medicine *Andrographis paniculata Nees* on mice, rats, and rabbits. This abortifacient decreases the blood flow in the uterus and inhibits DNA synthesis by decidual tissue. At the Nanjing Institute of Materia Medica, Chinese scientists are investigating the use of a saponin from the pod-bearing tree *Gleditsia sinensis* as a mid-term abortifacient (161).

### New Male Methods

In early 1971 a group of medical scientists from the Chinese Medical University (successor to the well-known Peking Union Medical College) discovered that gossypol, a chemical derived from cottonseed, can reduce male sperm counts. Their research was triggered by an outbreak of illness and impaired fertility among Chinese farmers exposed to raw cottonseed oil after a change in processing techniques. A series of studies on rats, mice, dogs, and monkeys identified gossypol as the agent responsible for both the toxic effects and a reduction in fertility (307, 323).

In clinical trials from 1972 to 1977, 8,806 men were treated with gossypol, half for more than two years. The drug reduced sperm counts to less than four million per ml in 99.1 percent of the subjects. (Between 40 and 250 million per ml is considered normal.) These clinical trials raised some questions about side-effects and the return of fertility. Twelve percent of the subjects suffered from fatigue, 7 percent experienced gastrointestinal symptoms, 6 percent reported reduced libido, and there were 66 cases of hypokalemia (extreme potassium depletion) requiring hospitalization. Furthermore, 25 percent of the 2,000 subjects followed up after the end of treatment did not show a return of normal sperm counts (325). An investigation of the cases of hypokalemia showed that they occurred in men whose diets were low in potassium and could be prevented by giving postassium salt to men who complained of fatigue and weakness (343).

Work on this potential male pill continues (436). In April 1980 the Chinese Academy of Medical Science arranged to collaborate with The Rockefeller Foundation on an evaluation of gossypol, funded partly by the UN Fund for Population Activities (UNFPA), in sample hospitals in China and elsewhere. Gossypol may also have applications for female contraception. In women the drug is known to cause amenorrhea and degenerative changes of the endometrium (440). Experiments in the United States and Finland show that small amounts of gossypol applied locally can inhibit sperm motility, making it a potential active ingredient for vaginal creams or suppositories (35, 317, 350). The Chinese are trying to develop a gossypol pill that could be taken by men or women; husband and wife could alternate taking the pill and thus share any health risks (35).

As early as 1964 researchers began to explore another method of male contraception: thermal treatment of the testes with hot baths, microwaves, laser beams, or supersonic radiation to suppress the normal growth of sperm. Animal experiments and clinical trials carried on in more than 10 provinces have shown promising results. Hunan researchers found that exposing the testes to temperatures of 42° to 43°C for 15 minutes daily for one to two weeks supressed spermatogenesis for three to six months (389). In another experiment, conducted by the Chongqing Municipal Birth Planning Guidance Institute, the testes of 92 men were exposed to microwaves an average of 3.5 times over a 43-day period. The average sperm count of 72,840,000 per ml before treatment was reduced to 225,000 afterwards, while the sperm survival rate fell from 60.6 to 8.3 percent. In 14 men the sperm count was reduced to zero (433). A scientific research coordinating group established in August 1981 is promoting further research into this approach to male contraception.

In summary, China's birth planning programs have vigorously promoted the IUD and sterilization, and these two methods together account for about 80 percent of all contraceptive practice. Widespread use of highly effective contraceptive methods, together with the rigorous enforcement of the late marriage norm and the relatively high induced abortion rate, largely explains the relatively low crude birthrate of 18 to 22 per 1,000 in China in recent years despite the large proportion of men and women in their early reproductive years. Meanwhile research continues to look for ways to meet the particular contraceptive needs of Chinese society with methods that are effective, inexpensive, and feasible for in-country production.

## BIRTH PLANNING PROGRAM RESULTS

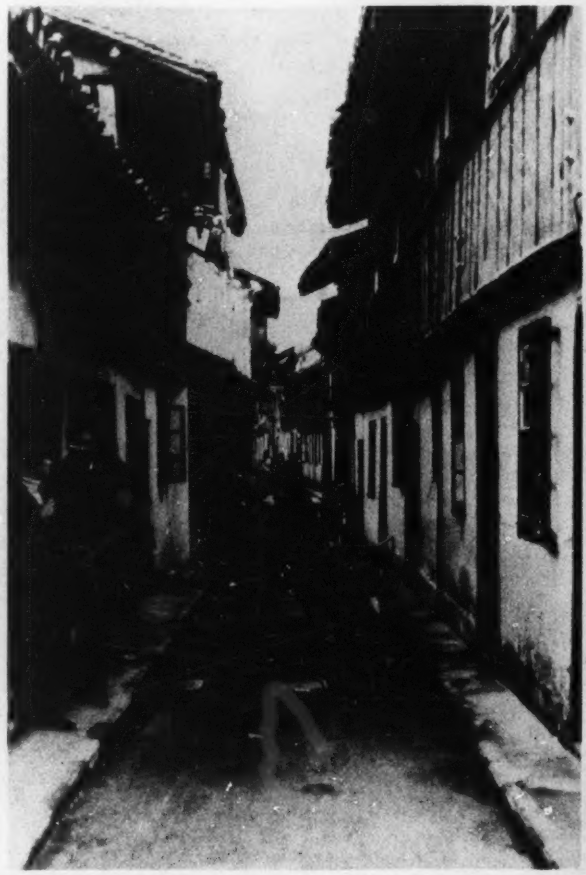
By vigorously promoting late marriage, rapidly increasing contraceptive prevalence, and terminating about one-quarter of all pregnancies, the third birth planning campaign reduced China's crude birthrate from 34 per 1,000 in 1970 to 18 per 1,000 in 1978 and 1979 (see Figure 1, p. J-579). Overall, the 50 percent decline in China's crude birthrate from 1962–65 to 1975–79 is unprecedented for a large developing country. Over the same period crude birthrates declined by 14 percent in India, 32 percent in South Korea, 33 percent in Taiwan, and 23 percent for all developed countries as a whole (399). The magnitude of China's fertility decline is even more remarkable in view of the country's low per capita GNP (about $250 US) and modest rate of economic development. Rapid declines in fertility elsewhere have usually taken place in the context of rapid economic growth. On the other hand, many social changes have provided a context favorable to major declines in fertility. The worst poverty has been reduced, since the benefits of development are distributed equitably. Enrollment in primary schools providing four years of education has been over 96 percent in recent years. The status of women is much better now than in the pre-1949 period (72, 155, 164, 434). Health conditions also have improved, as evidenced by a dramatic rise in life expectancy, estimated to be 63 or 64 in the mid-1970s (85).

Considering China's age structure and level of development, some outside observers have been skeptical of the official estimate of the birthrate and suggest the possibility of an extraordinary underestimate (71, 83). While underestimation is a possibility and the actual crude birthrate may be a few points higher than the official estimate, available program statistics are consistent with the official estimate.

### Quality of the Data

During the 1960s and 1970s demographic data on the PRC were very limited. For several decades the Chinese government did not expend much effort to develop reliable population statistics (242, 332). What figures were gathered have been generally regarded as national secrets, so data collected by censuses, surveys, and vital registration often were not released (71). In the face of this lack of data, speculations about the demography of China varied widely. For example, during the 1970s several well-publicized estimates of the country's population size ranged from 839 to 930 million; of the crude birthrate, from 14 to 37; of the crude death rate, from 6 to 13; and of the natural increase rate, from 8 to 24 (74, 82, 101, 242, 346, 377). While R.T. Ravenholt assumed that birth and death rates had dropped substantially by 1975 because of the vigorous birth planning program and advances in health and nutrition (346), John Aird, Judith Banister, and Leon Tabah emphasized the underregistration of births and deaths, the use of statistics from unrepresentative areas, and the fact that the age structure was unfavorable for any radical decline in the birthrate (74, 82, 377).

China's present leaders have lifted some of the restrictions on the release of population data, but the figures available are still



**Birth planning campaigns have been more successful in urban areas, where housing shortages and unemployment may make the disadvantages of large families more obvious.** (Courtesy of Robert Parker)

# THE 1982 CENSUS: COUNTING ONE BILLION PEOPLE

The third nationwide census in the history of China is scheduled for July 1982. It represents the largest such effort ever made, as millions of enumerators try to count about one billion people (175). Previous censuses were taken in 1953 and 1964. Data quality in those censuses has been questioned because officials had difficulty adhering to rigid schedules and local authorities often disregarded instructions or took short-cuts (71). This time the PRC has been so determined to take an accurate count for use in economic and social planning that the date for the census was repeatedly postponed to allow more time for thorough preparations (5, 7, 222).

Chinese planners have received technical assistance on census methodology from Japan, the Philippines, Canada, the United States, and the United Nations Statistical Office. They have collected a large library of published materials as well as copies of census forms in use abroad (71). The United Nations Fund for Population Activities (UNFPA) is providing $15 million (US) to establish computer centers for analysis and to give Chinese census officials special training (15). The total, 3-year budget for the census exceeds $135 million (US) (445).

### Careful Preparations

Preparations for the 1982 census have been elaborate. A temporary state census office, headed by Vice Premier Chen Muhua of the State Birth Planning Commission, opened in March 1981 (175). Similar census offices were established at every administrative level throughout China. To prevent omissions, each province has laboriously checked its residential registration records on a house-by-house basis (190, 201). The accuracy of this process, which might be affected by pressures to meet national birth planning targets, is crucial to the census results.

Training the large numbers of personnel needed has been a problem: more than six million enumerators and 4,500 data processors and key punch operators are needed and require training. In 1981 the national census office instructed every province, autonomous region, and municipality to carry out an experimental census, on the model of a 1980 national pretest in Jiangsu province, to train personnel, test the suitability of questions, and identify problems (7, 175, 181).

The completeness of the census depends upon mass understanding of and cooperation with the central government's directives. To ensure mass support, in 1981 the PRC launched a publicity campaign designed initially to mobilize Party and state departments on all levels. During the campaign's next stage, in 1982, census officials have used all media to make each household and individual understand what the census means. Publicity techniques were tested in the experimental censuses, then expanded nationwide (222).

As in 1953 and 1964, the 1982 census utilizes:

- a temporary national census office to direct the effort,
- a field check of households in advance to ensure that everyone is included,
- a census hour—midnight, June 30, 1982—to which all questions refer and which is standard throughout the country,
- heads of households in most areas coming to special registration stations (6),
- large numbers of enumerators going from door-to-door in areas where the population is scattered (71).

### Additional Data Collected

The 1982 census differs in some ways from past censuses. Methods for rechecking data will be standardized, rather than left to local discretion. Also, there will be twice as many questions on the census schedule. In addition to name, age, sex, ethnic identity, occupation, and education, some respondents are asked about place of birth, type of housing, and marital status. Some suggested questions are directly relevant to family planning. These include the number of surviving children and the number, sex, and birth order of all births during the previous year (7, 117).

Additional data on fertility and birth planning will be gathered by the PRC National Survey of Demographics and Birth Planning Practices, planned for 1982. This sample survey, involving all households in 650 brigades across the country, will gather detailed fertility and contraceptive histories. Although some Chinese universities have carried out similar surveys, this one is by far the largest ever attempted, with a sample size of 200,000 to 300,000 (109).

### Computer Technology

Computers will be used to expedite the processing of census data. In the past the Chinese carried out census computations manually, with abacuses (6). The 1982 census, however, will produce substantially more data than either of the two previous censuses, both because there are more people to be counted and because more questions are being asked of each person (222). Just inputting data on one billion people is a gigantic task, and it will be more complex because the new equipment—21 IBM computers provided by UNFPA and eight Wang computers purchased by the PRC—is unfamiliar (71, 445). These computers, one located in each provincial unit, will tabulate the data starting in September 1982 and continuing throughout 1983. Results will be analysed and published during 1984 (445).

The data processing system created for the census will be used afterwards in birth planning program evaluation and demographic research. It may even be expanded to include the civil registration system. This would give the PRC an accurate source of up-to-date population data between censuses (445).

The 1982 census will provide much needed demographic data. Past political policies in the PRC have made Chinese population data both scanty and of questionable accuracy. Claims of birth planning success have been disputed by some foreign scholars who argue that China's official statistics are unreliable (11, 270). A careful count in 1982 will help to determine how many people there are in China, how successful the birth planning campaigns have been, and how reliable the annual household registrations of population are.

incomplete and plagued with several problems (71). First, the figures released may be unrepresentative, selectively highlighting those areas making the most rapid progress in birth planning. (Figures from some of the most backward provinces, such as Guangdong, have now also been released, however.) Second, there are not enough qualified personnel in China to collect and analyze quantitative demographic data (157). Especially at the local level, many errors may be made (95). Third, registration of both births and deaths in developing countries is usually incomplete, making most estimates of vital rates too low. (It is difficult, however, to reconcile substantial and widespread underreporting of births with Chinese laws that make the allocation of food, housing, and education dependent on the registration of births (316, 345).) Fourth, local officials, under great pressure to meet their assigned birth quotas and natural increase targets, may systematically falsify population figures (73). The absence of independent monitoring by means of sample surveys or spot checks makes the exaggeration of birth planning service statistics possible. In a recent article an official in Jilin province openly complained about the practice of underreporting births in order to show "accomplishment" in birth planning. Local units routinely reported natural increase rates that were lower than actual rates (298). Because of these problems, both Chinese officials and outside demographers have expressed doubts about the reliability of the population figures released by the PRC (175).

There is increasing evidence, however, that the official figures are reasonably accurate. One recent visitor to the PRC, who relied on somewhat unsatisfactory translators, has reported that Chinese officials on the local level seemed unconcerned and careless about statistics (94), but two recent field studies, conducted by outside researchers to check the accuracy of local figures, have proved them to be of high quality. William Lavely, comparing the service statistics of a commune in Shifang county, Sichuan province, with the results of his own fertility survey, found in a preliminary analysis that the two are closely matched (283). Leslie Corsa and Pi-chao Chen, working in Huaide county, Jilin province, subjected local birth planning data to multiple checks for internal consistency and found them extremely accurate (103). Of the service and registration statistics made available to them, Corsa and Chen found that only infant mortality was obviously undercounted, due to differences in the definition of live birth and the practice of not registering births and deaths of infants who die shortly after delivery. Because of the much reduced infant mortality rate now prevailing in China (about 50 per 1,000) (85, 114, 450), however, the underregistration of infant deaths should not affect the overall crude death rate greatly. (Marriages also were underregistered.)

Still, it is impossible to generalize on the basis of only one county and one commune. Perhaps the first of a regular series of sample surveys monitoring local service statistics, scheduled to be undertaken by the Chinese in July 1982 with support from the United Nations Fund for Population Activities (UNFPA), will better answer the question of reliability.

Demographers working with national data have generally concluded that the officially announced decline in fertility is real. Statistics on contraceptive usage, abortions, sterilizations, and school enrollment, as well as casual observation, corroborate the birthrate figures (73, 95). Ansley Coale, comparing Chinese data on age structure and birth registrations from a variety of sources, concluded:

> The birth rate of 18.3 per thousand [in 1978], and the implied total fertility rate of 2.4, may thus be understatements. But the approximate consistency of the various figures (imperfect though we have noted them to be), including the age pattern of fertility, supports a belief that a remarkably low level of childbearing has been reached in China. (156)

### Birth Planning Statistics

National statistics on the decline in the crude birthrate and natural increase rate during the 1970s show the substantial impact of the third birth planning campaign (see Table 6 and Figure 1, p. J-579). The crude birthrate fell by almost 50 percent from 1970 to 1979, from 33.6 to 17.9 per 1,000 population. During this period the relatively low rate of mortality already achieved in China dropped even further, from 7.6 to 6.2 per 1,000. Thus the rate of natural increase fell from 2.6 percent to less than 1.2 percent over the decade.

**Table 6. Population Totals and Vital Rates, People's Republic of China, 1949–1979**
(absolute numbers in 1,000; rates per 1,000 population)

| | Population | | Vital Rates | | | Reference Number | |
|---|---|---|---|---|---|---|---|
| Year | Year-End | Census Total | Crude Birth-rate | Crude Death Rate | Natural Increase Rate | Population | Vital Rates |
| 1949 | 541,670 | | | | | 149 | |
| 1950 | 551,960 | | 37.00 | 18.00 | 19.00 | 149 | 459 |
| 1951 | 563,000 | | | | | 149 | |
| 1952 | 574,820 | | 37.00 | 17.00 | 20.00 | 149 | 459 |
| 1953 | 587,960 | 582,603* | 37 | 14 | 23 | 149 | 383 |
| 1954 | 601,720 | | 37.39 | 13.18 | 24.79 | 149 | 383 |
| 1955 | 614,650 | | 32.60 | 12.28 | 20.32 | 149 | 383 |
| 1956 | 627,800 | | 31.90 | 11.40 | 20.50 | 149 | 383 |
| 1957 | 646,530 | | 34.03 | 10.80 | 23.23 | 149 | 459 |
| 1958 | 656,630 | | 29.2 | 12 | 17.2 | 145 | 383 |
| 1959 | | | 24.8 | 14.6 | 10.2 | | 383 |
| 1960 | | | | 25.4 | | | 374 |
| 1961 | | | 18.1 | 14.3 | 3.8 | | 383 |
| 1962 | | | 37.33 | 10.08 | 27.14 | | 459 |
| 1963 | | | 43.60 | 10.10 | 33.50 | | 383 |
| 1964 | | 691,220* | 39.3 | 11.5 | 27.8 | | 383 |
| 1965 | | | 38.1 | 9.6 | 28.5 | | 383 |
| 1966 | | | | | | | |
| 1967 | | | | | | | |
| 1968 | | | | | | | |
| 1969 | | | | | | | |
| 1970 | | | 33.59 | 7.64 | 25.95 | | 459 |
| 1971 | | | 30.74 | 7.34 | 23.40 | | 459 |
| 1972 | | | 29.92 | 7.65 | 22.27 | | 459 |
| 1973 | | | 28.07 | 7.08 | 20.99 | | 459 |
| 1974 | | | 24.95 | 7.38 | 17.56 | | 459 |
| 1975 | 919,700 | | 23.13 | 7.36 | 15.77 | 147 | 459 |
| 1976 | 932,670 | | 20.01 | 7.29 | 12.72 | 147 | 459 |
| 1977 | 945,230 | | 19.03 | 6.91 | 12.12 | 147 | 459 |
| 1978 | 958,090 | | 18.34 | 6.29 | 12.05 | 147 | 459 |
| 1979 | 970,920 | | 17.90 | 6.24 | 11.66 | 146 | 459 |
| 1980 | 982,555 | | | | 12 | 142 | 142 |

*Sources for census totals: 1953 (144), 1964 (363)

In the middle of the Third Campaign, in addition to standard vital statistics rates, a distinctive set of Chinese statistics was developed to evaluate program performance. This system, first developed in the major cities of the Yangtze delta, measures the extent to which eligible couples of a community or unit have complied with the three reproductive norms. The new measures are the late marriage rate, the planned birth rate, and the birth limitation rate (see p. J-590). Chinese officials use these rates to compare the performance of birth planning programs in geographical administrative units. Over time, these indices can reveal improvements or failings in program performance.

**Table 7. Late Marriage Rate, Birth Limitation Rate, Planned Birth Rate, and Crude Birthrate for the People's Republic of China and Selected Provinces, 1977–1980**

| Place & Year | Ref. No. | Late Marriage Rate (%) | Birth Limitation Rate (%) | Planned Birth Rate (%) | Crude Birthrate (per 1,000 population) |
|---|---|---|---|---|---|
| **China 1978** | 115 | | 70* | | 18.34 |
| **Gansu province 1979** | 132 | 92.0 | 83.7 | 60.8 | 16.6 |
| **Guangdong province 1980** | 134 | 87.6 | 73.0 | 66.2 | 20.2 |
| **Hebei province 1977** | 135 | 93.0 | 83.0 | 77.0 | 15.0 |
| **Jiangsu province 1977** | 137 | 88.5 | 83.7 | 60.8 | 15.99 |
| **Shaanxi province 1980** | 139 | | 86.1 | 90 | 14.0 |
| **Beijing municipality 1978** | 342 | | | | 12.92 |
| **City proper 1978** | 342 | | | | 9.73 |
| **Periurban counties 1978** | 342 | | | | 16.72 |
| **Shanghai municipality 1979–80** | 53 | | | 80 | |
| **City proper 1978** | 140 | 90.0 | 85.0 | 85.0 | 7.4 |
| **Periurban counties 1978** | 140 | 80.0 | 80.0 | 75.0 | 15.3 |
| **Tianjin municipality 1978** | 309 | 95.0 | 80.6 | | 15.42 |
| **City proper 1978** | 309 | 96.6 | 88.8 | 88.5 | 10.8 |
| **Suburban 1978** | 309 | 94.9 | 75.9 | 57.2 | 19.0 |
| **Rural 1978** | 309 | 93.2 | 73.0 | 63.6 | 18.9 |

**Late Marriage Rate:** Percentage of couples marrying in the year who marry at or after the ages set by the late marriage norm.
**Birth Limitation Rate:** Roughly, the percentage of married couples under age 50 using contraception. Use for any portion of the year is included in the numerator, and naturally infertile couples are excluded from the denominator.
**Planned Birth Rate:** Percentage of couples complying with all three birth planning norms.

*Estimate based on regression equation derived from crude birthrates and birth limitation rates in selected areas of China

### The Late Marriage Rate

The late marriage rate measures the extent to which newlyweds have complied with the late marriage norm. It is defined as the percentage of the couples married in a calendar year who marry after age 25 for men and 23 for women in rural areas and after age 28 and 25, respectively, in urban areas. Because of variations in the recommended age, these rates may not be precisely comparable. By the late 1970s, well over 70 percent of China's population was reportedly conforming to the norms (see Table 7). Even in Guangdong province, where the birth planning program has been persistently among the worst (29), the late marriage rate was 75 percent.

On the basis of interviews with refugees in Hong Kong, an admittedly unrepresentative sample, William Parrish and Martin Whyte estimate that the average age at marriage among Guangdong peasants rose from 20 in 1950–58 to 21.1 in 1968–74 for females and from 24.5 to 24.8 for males (336). Their estimates are low compared with more recent data released by Chinese sources. According to these sources, in Shanghai municipality the mean age at first marriage for females rose from 19.9 in 1950 to 27.9 in 1975–79 in the city proper and from 19.8 to 25 in periurban counties (246). For the whole municipality, women's age at first marriage has averaged 25.5 in recent years. According to a stratified sample survey conducted by a Shanghai medical college and the municipal birth planning office, 51 percent of women aged 25–29 in the city proper are single and 83 percent of women aged 20–24 in the periurban counties are single (53). A sample survey of 5 percent of the women being married in Beijing municipality showed that 99.4 percent in the city proper did not marry before they reached 25 years of age and 99.8 percent in the periurban counties did not marry before they were 23 years old (437). In the municipality of Tianjin, births to women younger than age 25 accounted for only 1.1 percent of all births in 1978, suggesting that few women married before age 24 or, if they did, they delayed their first births (309). The rustication program is partially responsible for this rise in the age at marriage in urban areas. Young people sent to the country to work waited to marry until they were allowed to return to the city after the fall of the Gang of Four.

The Chinese late marriage rates in Table 7 may be compared with rates for other East Asian countries. In 1975 the comparable rate for women in Taiwan was 35 percent; in Hong Kong, 37 percent; in Singapore, 36 percent; and in Japan, 42 percent. The mean age at marriage in these countries in the mid-1970s was between 23 and 25—high compared with that in most developing countries (378, 398). None of these countries has emphasized late marriage as an element of family planning programs, although age at marriage has risen in all of them (458).

### Planned Birth Rate

The planned birth rate measures the extent to which couples conform to all three reproductive norms. Because of local variations in these norms, however, as well as changes in national policy, the planned birth rate is not a good measure for comparing different areas or even assessing change over time. Currently, "planned births" may be best defined as those births authorized by the planned birth cards issued by each county or municipal birth planning staff office (see p. J-587). On the basis of the few figures available, it seems that a high percentage of the population is conforming to the three norms. Of areas with reported rates, Tianjin municipality leads with a planned birth rate of 92 percent, and Jiangsu and Gansu provinces bring up the rear with rates of 60.8 percent (see Table 7).

Another measure of success is the percentage of births of third and higher birth order (see Table 8). Of the total 17.4 million births in 1978, third and higher parity births accounted for 30 percent. By 1980 that figure had dropped to 20 percent (291). The comparable figures for cities with available data are even lower: 5 percent in Changsha, Hunan province; 15 percent in Chengdu, Sichuan province; 10 percent in Shanghai municipality and 2 percent in the city proper of Shanghai (136, 140, 141). By comparison, in Taiwan the percentage of births that were third or higher order was 37 in 1976 (378). While the Chinese figure is low compared with those for other countries, it indicates that in 1978, despite government pressures, almost one of every three births was not officially sanctioned.

### Variation in Results

The statistics show that the birth planning campaign has been more successful in some areas of China than in others. Major cites such as Tianjin, Beijing, and Shanghai reported progress early in the 1970s, while rural areas lagged behind (241). Table 9 shows about a 5-year lag separating urban and rural areas during the third birth planning campaign.

The 1978 municipal statistics for Shanghai and Beijing also illustrate the lead urban areas have taken in birth planning (see Table 7). The crude birthrates for the truly urban parts of these municipalities were 7.4 and 9.73, respectively, in contrast to rates of 15.3 and 16.72 for the periurban counties. In Beijing in 1978, 95 percent of the 10,084 births of third and higher order occurred in the periurban counties (342). In the cities it is easier to disseminate information and enforce national policy. Also, urban residents, confronted with an acute housing shortage and chronic unemployment, are more likely to see the direct connection between population growth and shortages of food, clothing, shelter, consumer goods, and jobs (73, 416). People who live in the country have more space, can spare some extra grain, and do not believe an extra child matters on the national level (345).

**Table 8. Percentage of Live Births by Birth Order During the Third Birth Planning Campaign, People's Republic of China, Selected Chinese Areas, and Taiwan, 1976–1978**

| Place & Year | Ref. No. | First Order Births | Second Order Births | First & Second Order Births | Third & Higher Order Births |
|---|---|---|---|---|---|
| **China 1978** | 115 | | | 70 | 30 |
| **Changsha city 1977** | 130 | 80 | 15 | 95 | 5 |
| **Chengdu city 1977** | 131 | 50 | 35 | 85 | 15 |
| **Guangdong province 1978** | 134 | | | 60 | 40 |
| **Shaanxi province 1979** | 269 | | | 68 | 32 |
| **Shanghai municipality 1978** | 140 | 70 | 20 | 90 | 10* |
| **Taiwan 1976** | 378 | 35 | 28 | 63 | 37 |

*In the city proper, third and higher birth orders accounted for less than 2 percent of total births.

**Table 9. Urban and Rural Crude Birthrates, People's Republic of China, 1971–78**
(per 1,000 population)

| | 1971 | 1972 | 1973 | 1974 | 1975 | 1976 | 1977 | 1978 |
|---|---|---|---|---|---|---|---|---|
| **Urban areas** | 21.9 | 20.1 | 18.1 | 15.1 | 15.3 | 13.6 | 13.9 | 14.0 |
| **Rural areas** | 31.9 | 31.2 | 29.4 | 26.2 | 24.8 | 20.9 | 19.7 | 18.9 |
| **National average** | 30.7 | 29.9 | 28.1 | 24.9 | 23.1 | 20.0 | 19.0 | 18.3 |

Sources: Urban and rural areas: Liu (299)
National: 1971, 1977, 1978: Liu (299); 1972–76: Li (459)

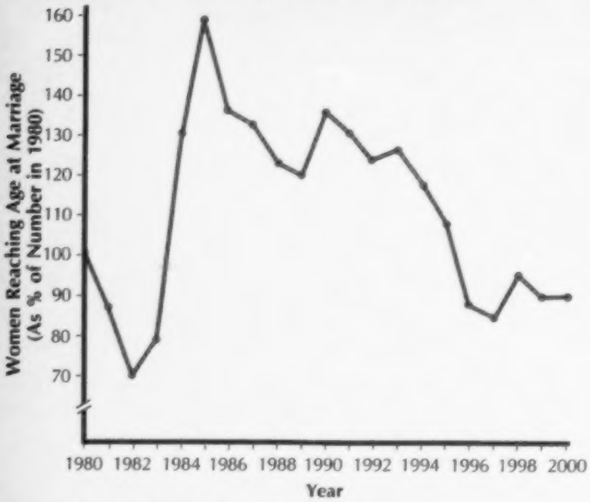
Regional variations in birth planning success also exist. The record of Hebei province, for example, is substantially better than that of Guangdong province. High rates of late marriage, birth limitation, and planned birth in 1977 clearly contributed to Hebei's low crude birthrate of 15.0, which was well below the national average of 18.3 (see Table 7).

Several factors may explain differences. Recent analysis has showed consistently lower birthrates in higher-income areas throughout the period of fertility decline in China. Education, employment opportunities, and health services all are more extensive in higher-income areas and thus may partially explain the relationship between low fertility and higher average per capita income (92). The link with income may be a reason for rural-urban variations in fertility, as well. Provincial success in birth planning also may depend on the proportion of minority inhabitants, who are treated differently by birth planning policies, and the commitment and effectiveness of the leadership.

## THE ONE-CHILD CAMPAIGN

The fourth birth planning campaign followed the third with no break in continuity. A change in policy and an intensification of birth planning efforts marked the transition in 1979, however. Economic goals were the primary force behind the shift in policy, as officials reasoned that continuing population growth would damage the ability of the PRC to carry out the "four modernizations" and to increase per capita GNP. The demographic reality was that the number of women reaching the age of marriage and reproduction was about to rise sharply. According to one Chinese demographer, beginning in 1984 the number of women reaching the age of marriage will increase sharply and will remain high until the 1990s (see Figure 3). Since over 25 million people were born each year between 1962 and 1972, the PRC can expect more than 12 million marriages annually in the years to come (55). For example, statistics on births in the 1950s and 1960s show that roughly 9.63 million women reached age 22 in 1980; in 1984 this figure will rise to 12.05 million, and in 1985, to 14.5 million. In Guangdong province, for example, between 1977 and 1978 the an-

**Figure 3. Women Expected to Reach Age of Marriage* in the People's Republic of China, 1980–2000, as a Percentage of Number in 1980**



*Calculated to be age 22 by Coale (156)
Source: Liu (299)

**The large numbers of women reaching marriageable age in coming years means continuing rapid population growth for China unless a large proportion of couples choose to have no more than one child.**

nual number of first marriages had already jumped 60 percent—from 250,000 to 400,000 (293).

Chinese leaders perceive the one-child campaign as a sacrifice by the generations born in the 1960s and 1970s for the good of the country. Today's young couples are asked to cut back sharply on the size of their families in order to correct the demographic policy mistakes of the past—that is, the lack of a vigorous birth planning progra[illegible] the 1950s and 1960s. In effect, the one-child program is an attempt to prevent the baby boom of those years from repeating itself 25 years later (21, 225, 430).

The first stage of the campaign aims to reduce the natural increase rate to 5 per 1,000, or half of one percent, by 1985 by eliminating all births of third or higher order and persuading some families to have only one child. The second stage aims to reduce the rate to zero as soon as possible by extending the one-child norm (115). To help achieve the new goal of the one-child family, the government has designed an innovative package of incentives and disincentives to supplement the propaganda effort.

This program seems to be working, especially in urban areas. Despite problems in financing both the incentives and an adequate old-age security system, the proportion of couples who have pledged to have only one child continued to climb through 1981. First and second order births together accounted for 70 percent of all live births in the PRC in 1978 (115). By 1980 the percentage had risen to 80 (291). As a result, in many provinces and municipalities the natural increase rate is still falling despite the increasing number of married women of reproductive age.

### The One-Child Policy

In 1978 Vice-Premier Chen Muhua provided a statistical rationale for the one-child campaign. Noting that, in 1978, 30 percent of all births were third or higher parity, she concluded that eliminating only these births would reduce the natural increase rate from 12 to 7 per 1,000, short of the proposed target of 5 per 1,000 (115). If the target was to be reached, some couples would have to have only a single child. At that time, the national goal established was that 80 percent of all couples in the cities and 50 percent in the rural areas should have only one child, excluding, of course, those who already had more (342). Since then birth planning rhetoric has cited higher goals. In a February 1980 speech Chen Muhua stated:

> We will try to attain the goal that 95 percent of married couples in the cities and 90 percent in the countryside will have only one child in due course, so that the total population of China will be controlled at about 1.2 billion by the end of this century. (170, 176)

Some Chinese leaders opposed vigorous pursuit of the one-child policy. During the National People's Congress held in the summer of 1980, delegates were divided over the issue (64). Two factions led the opposition. Rural delegates argued that the one-child policy jeopardized old-age security—parents could not rely on a single child for support in later years, especially if that child was a girl. At the same time, army officers feared a dearth of young male recruits, which would cripple China's ability to resist a Soviet threat (91). Military leaders argued that families would be reluctant to allow only sons to serve in the army—especially if they were only children, too (77). Because of a lack of consensus among the leadership, the National People's Congress did not pass a proposed law instituting incentives and disincentives, and instead the CCP Central Committee compromised by issuing an open letter to all Party and Communist Youth League members endorsing the one-child campaign. In the letter the Party elite called on all Party and Communist Youth League members, especially the cadres, to "take the lead" in responding to the new policy, offer a good example to the rest of the nation, and "actively, conscientiously, and patiently publicize the call among the broad masses" (174).

The call for a one-child family is a compromise between the government's desire to reach zero population growth and Chinese social realities. To reduce the natural increase rate to zero in a decade or two would mean that many people could not have any children. China's leaders have recognized the impossibility of such a plan, since universal marriage and reproduction is culturally mandated and economically important to individual households. The goal of a one-child family is a calculated risk: the government believes that it is the most extreme reduction in fertility tolerable to the people. While the one-child family is possible, having no children at all would be "impractical and infeasible" (414).

### Changing Contraceptive Use

The one-child campaign may be affecting couples' preferences for one contraceptive method over another. Data from Shanghai suggest that now fewer women are willing to be sterilized. Instead, they are choosing reversible methods, such as the pill or the IUD. This allows them to have a second child should the first die or be disabled (335). One neighborhood committee in an industrial section of Shanghai also is encouraging the use of the IUD in place of oral contraceptives. The committee is concerned that steroids are unsafe when used by women for such a long period of time as the one-child norm would require (91).

At the same time, the demands of the one-child campaign may lead the program to emphasize even more the long-term, highly effective methods—the IUD and sterilization. The need for a safe, long-term, reversible method of birth control currently is stimulating contraceptive research in China.

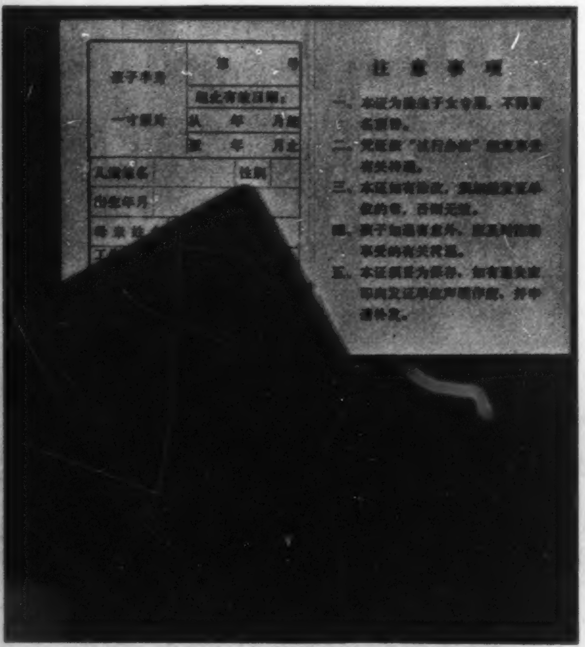
### Incentives

In 1979 Chen Muhua called for an economic reward and punishment scheme to promote the one-child family. That same year Chinese officials proposed a National Birth Planning Law to provide incentives for the one-child family and disincentives for more than two births. During 1980, the eighth draft of the law circulated at the grassroots level to gather comments and reaction, but the National People's Congress (NPC) of September 1980 did not approve the draft. Peng Zheng, the vice-chairman of the Standing Committee of the NPC, explained:

> . . .because birth planning work is still new to us, because there are still many unresolved problems despite the good results and rich experience in our work of recent years, and because the draft is not the result of the consensus of all quarters, we decided that the time is not ripe for enacting the law. (337)

The unresolved problems Peng referred to are probably the punitive provisions in the draft applying to third and higher parity births. If there was widespread noncompliance with the law in rural areas among peasants who would not stop childbearing until they had at least one son, how would the government react? Could it enforce punitive measures against large numbers of the population? Furthermore, the law calls for generous rewards to couples who pledge to have only one child. How could these rewards be financed on a large scale?

Instead, provinces have been encouraged to proceed on their own without national legislation. Taking the draft of the birth planning law as a point of reference, many provinces have drawn up and promulgated their own measures. Although the specific incentives offered vary from one province to another, they all consist of substantial economic and noneconomic incentives to one-child couples who pledge to have no more.



**This one-child certificate from Shanghai would identify a family with one child who pledged to have no more. Such certificates entitle families to benefits such as extra income and free health care.** (Courtesy of Carl Taylor and Robert Parker)

Benefits and incentives vary even within a province. Taking provincial measures as the guideline, individual counties, brigades, or even factories can add their own local incentives.

Couples are eligible for a one-child certificate after their first child (see photo, this page). Upon applying for and obtaining the certificate, the couple and their child are entitled to the benefits specified by local law. These benefits might include:

**Income**
- in urban areas parents receive a monthly stipend, ranging from 5 to 8 percent of the average worker's wage, that continues until the child reaches age 14,
- in rural villages parents receive as much as an extra month's work points a year until the child reaches age 14,
- in rural communes the child receives an adult's grain ration and counts as 1.5 to 2 persons in the allocation of private farming plots.

**Housing**
- living space equal to that for a 2-child family,
- preferential treatment when applying for public housing in urban areas.

**Health**
- two weeks of extra paid maternity leave,
- highest priority in receiving health care for the child.

**Old age**
- in urban areas a supplementary pension over and above that provided by the current labor protection law,
- in rural areas a guaranteed standard of living equal to or higher than the local average.

**Children's education**
- highest priority in admission to nurseries, kindergartens, and school programs,
- exemption from tuition costs and extra expenses from primary school through senior middle school.

**Children's jobs**
- highest priority in receiving desired job assignments when they grow up (65, 195, 228, 248, 292, 355, 451–7).

A survey concerning the one-child program, conducted in 1979 in an 8-block area of Hefei city, Anhui province, revealed some problems in the implementation of economic rewards (80). Great disparities existed among the incentives offered by various employing units and were a source of considerable dissatisfaction among the people. Poor units might offer "a couple of towels, a thermos bottle, some toys, a washing basin, or nothing at all," while more profitable enterprises paid substantial money bonuses and supplied free health care and schooling to the only children. The better housing promised to certificate holders had not materialized at all. Some units ignored the housing priority assigned to the certificate holders, while in other areas the buildings themselves were nonexistent. Also, many benefits lose their value when the majority signs up for the one-child certificates. For example, priority in health care or jobs means little when it is shared with 70 percent of all couples. Perhaps because the economic rewards of the one-child certificate had proved illusory, the survey reported that

> families with financial difficulties [were] most likely to refrain from applying for [the] certificate or to waver in thought after receiving certificates. (80)

Poor families most concerned with economic issues were not convinced that the one-child pledge would improve their standard of living.

# ONLY CHILDREN, BETTER CHILDREN?

During the third birth planning campaign (1971–79), Chinese authorities intensified efforts to improve maternal and child health care. Officials believed that parents would be more willing to have fewer children if they expected those children to survive and grow up in good health (415). Antenatal and obstetrical care was upgraded. For example, health workers identified high-risk women during pregnancy so that they could deliver in well-equipped hospitals. Proper techniques for handling the umbilical cords of newborns were introduced, thus eliminating neonatal tetanus (421). Premature babies were followed up intensively. Child health stations began providing preventive care, such as vaccinations against tetanus, measles, polio, tuberculosis, diphtheria, pertussis, and the like. As a result of these and earlier efforts, infant mortality declined from over 200 deaths per 1,000 births in 1949 to about 50 by the mid-1970s (85, 114, 450). In some areas health workers now check on infants in the home and on young children at nurseries and kindergartens. They also give mothers advice on hygiene and nutrition (321, 421).

As average family size becomes smaller, children become more precious and parents become increasingly concerned that their children be "perfect" (335). In keeping with the one-child campaign, begun in 1979, the slogan of the third birth planning campaign has been expanded to *wan xi shao you*, "later, longer, fewer, and better." Even more emphasis has been placed on maternal and child health. For example, in Shifang county, Sichuan province, children from one-child families receive routine monthly health check-ups, take first priority in clinics, and can use special registration desks and pharmacy windows in the health centers (292). In addition, interest in education, psychological problems, and childhood diseases is increasing.

Recently Chinese officials have also expressed interest in genetic matters such as the frequency of abnormal births and genetic counseling to avoid such births (91, 342). Marriages are forbidden between close blood relations. Individuals whose children could develop hereditary diseases are persuaded not to have any. Reportedly amniocentesis is widely used (446). In a 1981 speech Vice-Premier Chen Muhua said:

> Eugenics is also an important aspect of planned parenthood. Do not give birth to physically unhealthy or mentally retarded children, for that will put more burdens on the family and society and make the state and nation lose time. (177)

Pamphlets on sex education and contraception that are routinely distributed to newlyweds now contain information on genetics; questions about the physical status of prospective mothers have appeared in surveys of birth planning practices (109, 413). Genetic research institutes are being set up, and counselors are being trained.

Current birth planning rhetoric often refers to the need to improve "the quality of the population." This phrase is directed at educational opportunities as well as at eugenics and health care. According to a speech by Xu Dixin, President of the Chinese Population Association, at the opening of the Third National Conference of Population Science in 1981, only 0.5 percent of the population is college-educated and only 22 percent reached the middle-school level. There are shortages of teachers, educational materials, and school buildings (428). Under these circumstances, and in a country where traditionally learning has been highly valued, Chinese families prize the educational rewards of the one-child certificate (292). According to a Chinese newspaper article, many would rather have a single well-educated child than two or three poorly educated children (431).

Chinese officials express a growing interest in the psychosocial implications of the one-child family (411). They are concerned that only children might be spoiled and pampered by their relatives and have behavioral problems in school (91, 281, 428). The 1979 survey of one-child families in Hefei city, Anhui province, warned that

> most of the single children are well-developed, but, due to favorable economic conditions as well as love and overindulgence on the part of parents and grandparents, some of them tend to be willful, selfish, and even eccentric. (80)

Parents of only children are urged to cooperate with the schools to solve this problem. Also, Chinese officials have recommended that government departments publish pamphlets and hold child psychology classes to teach parents how best to raise their only children (80, 428).

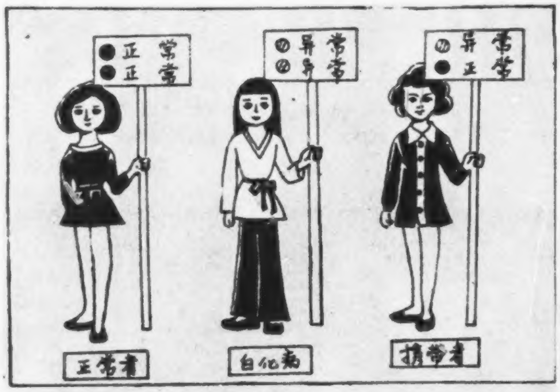
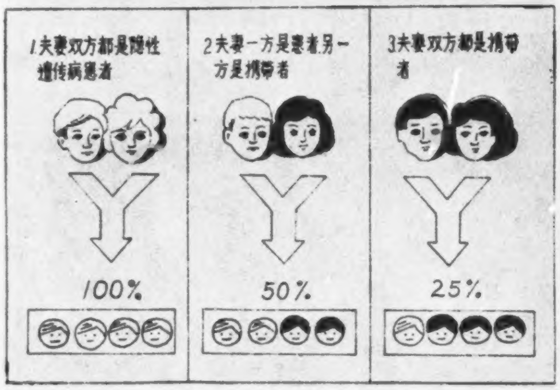


图 8



**The one-child campaign has generated more emphasis on child health, including greater concern about genetic diseases. This drawing from a pamphlet for newlyweds shows how a recessive trait (albino coloring) is inherited.** (Courtesy of John Chao)

Economic incentives complement but do not replace persuasion and educational work. The themes used in the one-child campaign are different, however, from birth planning themes used earlier. Appeals cite national concerns rather than personal and familial goals. Editorials urging birth planning now describe it as a "strategic task" important for "the development of our national economy," "the Chinese nation's prosperity," "the speed and future of the four modernizations," and the "health and happiness of generations to come" (174, 226). Chen Muhua, announcing the one-child campaign in 1979, explicitly stated that the interests of individuals must "voluntarily be subordinated" to the interests of the state (115).

In order to overcome the traditional Chinese desire for a son to provide support in old age, the government has designed additional incentives for the one-daughter family. In old China a daughter was a transitory asset because she went to live with her husband's family after marriage and never contributed to the welfare of her own parents when they grew old (417). Hence the saying, "a daughter who has been given away in marriage is like spilt water" (241). Chinese parents are less likely to stop at one child if the first is a girl. The 1979 survey in Hefei city found that the reason most often cited for not applying for the one-child certificate was the desire for a boy (80). To try to solve this problem, officials are now encouraging young men to move in with their in-laws when they marry an only daughter. (This strategy has worked in a few cases, but the traditional pattern of living with the husband's parents still prevails.) Also, daughters are now legally responsible for their parents' welfare in the same way as sons. A daughter as well as a son may now take over the father's job when he retires, and job preference in general is given to children from one-child families and to girls who have no brothers (13, 65). According to a recent law in Guangdong province, property can be distributed to daughters as well as to sons; the brigade or commune must supply building materials to the father of an only daughter when he wishes to build a house; and there are special celebrations each time a man settles with his wife's family (2).

**A sign of the rapid shift to the one-child family in China: a Beijing woman takes her grandson for an outing in a pram built for two.** (Courtesy of Stewart E. Fraser)

### Penalties

Just as the state rewards one-child families for restricting their fertility, it penalizes those who do not comply with government policy. There is wide provincial and local variation in the penalties, but these are among the most common: Parents who break their pledge by having a second child are required to return all the stipends or work points they have received. If any couple has a third child, their monthly wages are reduced by 10 percent or more, and they must remain in housing meant for a 2-child family. Families with more than two children do not receive subsidies when they are in financial difficulties, and they are charged for the pregnant mother's medical care and the extra child's grain ration (292). The child cannot enroll in any cooperative medical care scheme and receives no preference in school and job assignments (248). Regulations in Guangzhou make those who violate birth planning norms ineligible for three years for job promotions, wage increases, production awards, and participation in worker competitions (4). Multiple births are an exception to these rules. Also, if an only child dies, the parents may have another without penalty.

In some areas, such as Shanghai, where the one-child campaign is intensely promoted, the government now penalizes second as well as third and higher births. Municipal regulations permit parents to have a second child without penalty only if the first child has a disabling disease, is the child of an earlier marriage, or was adopted because of the woman's presumed sterility (228, 235).

The incentives and disincentives of the one-child campaign have to some extent reversed China's welfare policy. Before 1978 official regulations governing the distribution of housing, welfare subsidies, grain rations, and private farming plots favored large families. The pronatalist effect of the earlier regulations has therefore been reversed.

The penalty systems are indicative of China's new, more urgent attitude toward birth planning. The resolve expressed by birth planning rhetoric has hardened, as illustrated in this 1981 provincial policy statement:

> We must continue to commend and reward couples who have only one child, strictly control the birth of a second child and resolutely put a stop to the birth of a third. We must mobilize couples of child bearing age to implement effective contraceptive measures, fine those who violate planned parenthood, and punish those who sabotage it. (184)

Reports from Sichuan province state that many people have been treated as criminals for activities harmful to birth planning (43). Complaints in the local media describe women who are forced to accept contraception or abortion (192, 210), and there are even reports of the abandonment or drowning of female babies (17, 150, 411). A recent, revealing circular issued by the Ministry of Justice announces sanctions against "people who sabotage birth control plans by removing women's intrauterine contraceptive devices" (208). Evidently women who submit reluctantly to IUD insertion are paying to have the devices removed with homemade wire hooks, since most Chinese IUDs lack strings (104, 173). In one district of Guizhou province, more than 6,700 women (over 30 percent of those fitted with IUDs) reportedly had their IUDs illegally removed (422).

National policy statements continue to reject coercion, however. In his 1980 speech at the Third Session of the Fifth National People's Congress in Beijing, Chairman Hua Guofeng deplored the use of compulsion and arbitrary orders and described them as local aberrations in violation of national policy (261).

### Results of the One-Child Campaign

So far, the progress of the one-child campaign exceeds the National Birth Planning Staff Office's expectations, even though there is considerable local variation and some evidence of resistance. The Office was discouraged initially by the results of a 1979 opinion and attitude survey conducted before the campaign's announcement (290). The campaign's progress, as measured by the newly created one-child certificate rate, has been impressive, however. This new measure is defined as the percentage of all couples with one child under age 14 who pledge not to have any more children. By 1979 over 5 million one-child certificates had been issued nationwide, achieving a 29 percent one-child certificate rate (70, 289). By June 1981 over 11 million certificates had been issued, covering 57 percent of the estimated total of 20 million Chinese couples with one child (20) (see Table 10). It is possible, however, that 20 million is an underestimate of the number of one-child couples. This would tend to inflate artificially the one-child certificate rate reported. On the other hand, the number of couples preventing a third birth in order to avoid penalties may be even greater than the number who agree to have only one child.

**Table 10. Couples Holding One-Child Certificates, in Absolute Numbers and as Percentage of All Couples with One Child, People's Republic of China and Selected Areas of China, 1979–1981**

| | | | | Couples Holding One-Child Certificates | |
|---|---|---|---|---|---|
| Place | Ref. No. | Type of Area | Date | Number | As % of All Couples With One Child |
| **China** | 20 | Nation | 6/81 | 11,000,000 | 57 |
| **Gansu** | 132 | Province | 12/80 | | 26 |
| **Guangdong** | 91 | Province | 1980 | | 29 |
| **Gangzhou** | 91 | City | 1980 | | 60 |
| **Rural counties** | 91 | Rural | 1980 | | 25 |
| **Heilongjiang** | | Province | | | |
| **Haerbhing** | 70 | City | 4/80 | 1,400,000 | 79 |
| **Jiangsu** | 70 | Province | 2/80 | 930,000 | 68.3 |
| **Suzhou** | 91 | City & suburban communes | 1980 | 27,550 | 95 |
| **Liaoning** | 211 | Province | 12/79 | 536,500 | 68 |
| **Shaanxi** | 139 | Province | 12/80 | | 80 |
| **Shandong** | 148 | Province | 3/80 | 1,170,000 | 77 |
| **Sichuan** | 91 | Province | 1980 | 1,800,000 | 81 |
| **Zhejiang** | 70 | Province | 12/79 | 120,000 | |
| **Beijing** | 90 | Municipality | mid-81 | 220,000 | 79 |
| **Shanghai** | 91 | Municipality | 1980 | 366,000 | 75 |
| **City proper** | 91 | | 1980 | | 82 |
| **Periurban** | 91 | | 1980 | | 61 |
| **Tianjin** | 29 | Municipality | 1/80 | 88,500 | 52 |
| **City proper** | 29 | | 1/80 | | 80 |
| **Periurban** | 29 | | 1/80 | | 30 |

The current numbers do not tell the whole story, however. The 1979 Anhui survey found that 10 percent of the certificate holders were not fully committed to the one-child family. These families might decide to return their certificates and have more children later. The survey report also mentioned the persistence of the traditional desire for sons and the difficulty of preventing women from giving birth over their 20 remaining reproductive years. According to this report, the birth planning policies had mixed results and would continue to face many obstacles in the future (80).

A similar survey in a rural area—Shifang county, Sichuan province—found that "20 to 30 percent of [the certificate holders] were quite persistent in their attitude toward having only one child, 10 percent of them might want to have another child, and the rest just followed the trend to apply" and were not fully committed to having no more children (292). In contrast, a 1980 survey of 19,207 one-child certificate holders in an urban Beijing district found that 74 percent were firmly committed, 23 percent just went along with the others, and only 3 percent were vacillating. One of those who were vacillating reportedly said, "I will put aside the one-child subsidies and wait and see if conditions will change" so that he could return the incentives if he changed his mind (252).

As in previous campaigns, results vary from one province to the next and from urban to rural areas. Urban areas consistently outperform the rural areas. In 1980 the rate of one-child certificates was 82 percent in the urban parts of Shanghai but only 61 percent in the periurban counties. Likewise, urban Tianjin had an 80 percent one-child certificate rate in contrast with 30 percent in the surrounding counties. In Guangdong province, often reprimanded for poor performance in birth planning work, the city of Guangzhou had a respectable one-child certificate rate of 60 percent in contrast to the rural average of only 25 percent (see Table 10). Only a few, atypical rural counties can match the performance of the cities with rates of over 90 percent, but these areas have consistently been pacesetters in birth planning work in rural areas (28, 44, 292). One major reason for the greater success of the one-child campaign in urban areas is the practice of withholding one-child benefits from all certificate holders for a month or a year each time any individual in a unit breaks his or her pledge. This generates strong peer pressure against potential violators.

The cities also lead the rural areas in another measure of birth planning success, the first-birth ratio, defined as the percentage of live births during a calendar year which are first births (see Table 11). For the PRC as a whole, the first-birth ratio in 1980 was 51 percent. Municipalities such as Shanghai and Beijing did considerably better, with first births making up 80 and 79 percent, respectively, of all live births in 1980. In the urban

### Table 11. Percentage of Live Births by Birth Order During the One-Child Campaign, People's Republic of China and Selected Areas of China, 1980

| Place | Ref. No. | First Order Births | Second Order Births | Third & Higher Order Births |
|---|---|---|---|---|
| **China** | 20 | 51 | | |
| | 291 | ——>80—— | | <20 |
| **Gansu province** | 132 | 57[a] | | |
| **Guangdong province** | 91 | 43 | 27 | 30 |
| **Shaanxi province** | 139 | 53 | | |
| **Sichuan province** | 91 | 70 | | |
| **Beijing municipality** | 90 | 79.4 | | |
| **City proper** | 90 | 90.3 | | |
| **Shanghai municipality** | 47 | >80 | <19.5 | 0.5 |
| **City proper** | 290 | 95[b] | | |
| **Periurban counties** | 290 | 75[b] | | |

[a] As of June 1981

[b] As of first quarter 1980

districts of Shanghai and Beijing the figures rose to 95 and 90 percent. Guangdong, as usual, lagged behind; the first-birth ratio was only 43 percent in 1980; third and higher order births accounted for 30 percent of all live births.

The success of the one-child campaign in large part explains the continuing fall in provincial natural increase rates. According to Chinese sources, as of December 1980 the natural increase rate was less than one percent in 18 provinces and municipalities (8). As Table 12 shows, exceptionally low natural increase rates are claimed in Zhejiang (0.4 percent), Shanghai (0.58 percent), Shaanxi (0.72 percent), and Tianjin (0.73 percent).

### Difficulties of the One-Child Goal

Despite achievements to date, there are serious problems inherent in the goal of a one-child family. Until China builds an adequate social security system in the countryside, it will be difficult to sustain a one-child rate of more than 50 percent over a long period of time. Peasants' preference for a son is not a curse of Confucian heritage but a rational calculation. In China today, as in the past, the average person looks to a son for support in old age (416). There is an adequate old-age pension system only for those employed in the state-owned, urban-industrial sector, and these workers constitute at most 10 percent of the total population. In rural areas the agricultural collective's "five guarantees"—food, shelter, clothing, medical care, and burial—provide only limited aid and are no substitute for the physical and psychological support provided by one's own child. Couples living with the bride's parents if her parents have no male child is not a solution. If an only son marries an only daughter, the couple can live with and take care of only one of the two sets of parents. At the same time, they must financially support both sets of parents, straining their resources relative to those who have only one set of parents to support. Therefore, it makes sense for parents to have a minimum of two children, regardless of sex. Presumably, even if the average peasant couple did stop at one child if the first was a boy, they would have a second child if the first was a girl. Given an almost even number of each sex at birth, in the long run no more than 50 percent of all couples are likely to have only one child.

The State Birth Planning Commission seems to be in agreement with this assessment. A recent Japanese delegation to China quoted Wan Soudao, a member of the Commission and the President of the Birth Planning Association of the PRC, as saying, "Our current program is aimed at reducing the average number of children per married couple to 1.5 on a step-by-step basis" (265). Assuming that all third and higher parity births are eliminated, a total fertility rate of 1.5 implies a 50 percent first-birth ratio. This suggests that Chinese leaders will be satisfied with something less than their expressed goal of nearly 100 percent one-child families.

Another problem with the implementation of the one-child campaign is financing. Where will the rewards come from? So far payments have been made by urban employing units and

### Table 12. Provincial Populations, 1979, and Natural Increase Rates, 1978–1980, People's Republic of China, Official Statistics

| | 1979 Population (in Millions)[a] | Natural Rate of Increase (per 1,000 Population) 1978[b] | 1979 | 1980 | Ref. No. for 1979/1980 |
|---|---|---|---|---|---|
| **National Total** | 971.074 | 12.1 | 11.66 | 12 | 459/142 |
| **SOUTHWEST** | | | | | |
| **Sichuan** | 97.74 | 6.1 | 6.7 | 4.45 | 320/91 |
| **Guizhou** | 27.31 | 16.0 | >15 | | 48 |
| **Yunnan** | 31.35 | 19.2 | 14.6 | 10.25 | 238 |
| **Xizang** | 1.83 | 14.2 | | | |
| **NORTHWEST** | | | | | |
| **Shaanxi** | 28.07 | 10.3 | 10.15 | 7.19 | 227/269 |
| **Gansu** | 18.94 | 12.2 | 10.8 | 8.9 | 182 |
| **Qinghai** | 3.72 | 19.5 | 18.0 | | 409 |
| **Ningxia** | 3.64 | 23.0 | 21.99 | | 427 |
| **Xinjiang** | 12.56 | 14.9 | 14.8 | 12.0 | 237 |
| **CENTRAL-SOUTH** | | | | | |
| **Henan** | 71.89 | 13.4 | 12.88 | 9.53 | 213 |
| **Hubei** | 46.32 | 10.5 | | | |
| **Hunan** | 52.23 | 10.4 | | 10 | 200 |
| **Guangxi** | 34.70 | 18.3 | >15 | | 48 |
| **Guangdong** | 56.81 | 14.8 | >16 | 15.0 | 29/91 |
| **EAST** | | | | | |
| **Shanghai** | 11.32 | 5.1 | 6.23 | 5.8 | 91 |
| **Jiangsu** | 58.93 | 9.5 | 8.78 | 6.25 | 77 |
| **Zhejiang** | 37.92 | 11.1 | <10 | 4.03 | 48/47 |
| **Anhui** | 48.03 | 13.8 | 13.74 | 9.9 | 77 |
| **Fujian** | 24.80 | 17.9 | 13.02 | 9.33 | 182 |
| **Jiangxi** | 32.29 | 19.6 | 13.74 | 9.11 | 204 |
| **Shandong** | 72.31 | 10.3 | 10.79 | 7.03 | 49 |
| **NORTH** | | | | | |
| **Beijing** | 8.70 | 6.8 | 7.71 | 9 | 77/90 |
| **Tianjin** | 7.40 | 9.2 | 8.66 | 7.25 | 77/235 |
| **Hebei** | 51.00 | 9.7 | <10 | 9.2 | 77 |
| **Shanxi** | 24.47 | 9.1 | | | 48 |
| **Nei Monggol** | 18.51 | 12.0 | 13.2 | 12.03 | 77 |
| **NORTHEAST** | | | | | |
| **Liaoning** | 34.42 | 12.6 | | 8.71 | 77 |
| **Jilin** | 21.84 | 14.3 | 13.89 | 9.65 | 206 |
| **Heilongjiang** | 31.69 | 12.2 | 10.14 | 8.6 | 77/197 |

[a] National and provincial populations from Sun Jing Zhi (460)

[b] Natural increase rates from Office of Birth Planning Leading Group of the State Council (17)

## BIRTH PLANNING: A RESPONSIBILITY TO OUR DESCENDANTS

"To reduce the natural increase rate to the level of zero or as near zero as possible—this is our historical responsibility to our descendants. . . . We ought to promote one child per couple in the next 30 to 40 years in a big way. This is an emergency measure we must resort to in order to overcome the consequences of rapid population increase in the 1960s and 1970s. It is also the price we have to pay to correct mistakes arising from past population policy [that is, ignoring birth planning] . . . . If we do not massively control population growth from now on, thus putting a brake on the momentum of rapid population increase, several decades from now we will face social problems which will be even greater and more serious. . . ."

Song Jiang,
Member of the Executive Committee of
China's Population Association,
1980 (368)

rural production teams. In the case of the production team, this means in practice that one-child families benefit at the expense of the rest. Poor production teams may lack funds to bestow rewards on a few without endangering the standard of living of the others. In the city some factories and businesses are unprofitable and find it difficult to pay wages; they cannot afford extra benefits, unrelated to productivity, for one-child families (80). Some rural officials have pointed out that one-child rewards cost the community less than the expenses of a second child (292), but payments of 60 *yuan* (about $36 US) or more a year to one-child families for 14 years are a major financial burden in an economy with a per capita GNP of only $250. In an October 1979 meeting several vice-premiers endorsed the idea of having the national government set aside funds to finance economic incentive schemes (290). Since that date, various provincial leaders and researchers have argued that national appropriations for national one-child incentives are indispensable and have recommended a change of government policy (9, 80). No final decision has yet been announced.

## CURRENT POLICIES

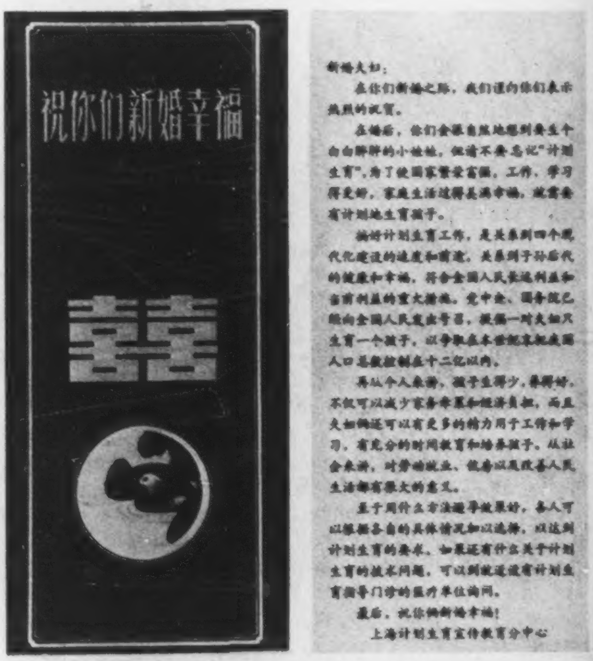
China's efforts to limit its population growth are not static. In the past, as political upheavals and ideological changes affected the government's population policy, one birth planning campaign succeeded another. More recently, statistical projections and demographic scholarship have shaped China's policies as both population scientists and political leaders realize the impact of the high birthrates of the past. The one-child campaign is a direct response to projections that the PRC's age structure will generate population growth for a long time to come if each young couple has two or more children. By 1981 two new policy trends with important implications for the future of birth planning were evident: a deemphasis on postponing marriage and a shift away from collective farming in rural areas.

### Changes in Age at Marriage

There are several clear signs that Chinese policy towards age at marriage is changing. Although China's new marriage law of 1980 actually raised the minimum age from 18 to 20 for women and from 20 to 22 for men, it did not adopt the officially recommended minimums of 23 and 25 (8, 423). Chinese officials considered raising the minimum legal age higher, but they decided that strict marriage restrictions only increased the incidence of premarital sex and illegitimate childbearing. In some areas many young people were flouting the norms by having a socially recognized wedding without legally registering the marriage (380). But, because the new marriage law failed to support the recommended ages, it can be interpreted as endorsing earlier marriage. For example, local authorities in the village of Zhuge in rural Hebei province had encouraged late marriage by decreeing that marriage licenses would be given only to men age 25 or older and to women age 23 or older. The 1980 national marriage law effectively reduced the local minimum age of marriage by three years (272).

One motive for allowing a decline in the age at marriage is probably concern over unrest in the large groups now reaching marriageable age. Early marriage may promote stability in a generation that is frustrated by a severe shortage of jobs (387). Also, the leadership wants to make the law more enforceable by recognizing the realities of the situation.

Although a lower age of marriage is now tolerated, later marriage is still encouraged (54). In Shanghai new regulations grant an extra week of honeymoon leave to urban men and women marrying over ages 27 and 25, respectively, and to rural men and women over ages 25 and 23 (228).



**The Shanghai Birth Planning Staff Office sends all newlyweds this card, which wishes them happiness on the front and explains the importance of birth planning on the back.** (Courtesy of John Chao)

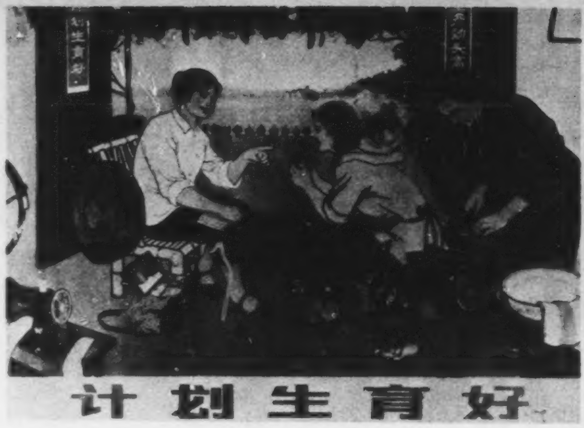
The lower age of marriage is combined with a new policy to delay the birth of the first and only child after marriage. In Beijing, for example, a public education campaign aimed at young people began in 1981 to teach them that the age for marriage may be different from the age for starting a family (54). In Shanghai women who wait to have their first and only child until age 25 in the city or age 23 in rural areas receive an additional 15 days of maternity leave (228). Also, couples who marry early receive a lower priority for a birth quota than couples who wait (109). Municipalities on a 3-year birth planning cycle have generally depended on a rule of thumb that allocates birth quotas to 25 percent of newlyweds in the first year after their marriage, 50 percent in the second year, and 25 percent in the third year. Major municipalities such as Shanghai now vigorously discourage early births after marriage and use a 15:55:30 ratio to allocate births among newlyweds (240).

In spite of these measures postponing first births, the combination of a lower age at marriage and the age structure of the population has already resulted in increases in the number of women marrying and giving birth. According to recent official data, there were 6.37 million marriages during the first half of 1981, nearly double the number (3.26 million) registered during the same period in 1980. Births totaled 6.39 million during the first half of 1981, an increase of 290,000 over the same period in 1980 (403). Thus, despite strenuous birth planning efforts, the number of births in 1981 is likely to exceed the 1980 level of 14.9 million.

### The Full Responsibility System

The second important policy change concerns the economic organization of the countryside. Since 1979 China's leaders have encouraged rural collectives to engage in nonfarming occupations, to increase the size of private plots, and to adopt new systems of management and production that give individuals a personal stake in collective farming (426). In the poorest areas, where the collective system is least well established, the peasants are choosing what is called the full responsibility system, which makes either the household or a crew of four or five households the unit of production, instead of, as before, the brigade or team. Each household or crew independently works the land assigned to it and turns over a specified portion of the crop to the state. An annual contract between each household or crew and the production team fixes the quota turned over to the state. Households may keep as profit whatever surplus they produce. Official sources report that peasants have so enthusiastically embraced this system that production is rising (63), but outside observers have cast doubt on the success of the system (100). Generally, this system has not been adopted where farming is highly mechanized or where collective agriculture has been profitable.

Some recent birth planning reports have called the full responsibility system a serious threat to birth planning—as serious as the increasing size of the population groups reaching marriageable age (30, 55, 365, 366). The new system gives the households a greater incentive to produce more children to work in the fields, earn money for the household, and support aging parents (55, 430). Moreover, households are reluctant to contribute to collective services, so that primary education systems and cooperative medical services are on the verge of financial insolvency in some areas (224, 225). This, of course, cripples the community distribution system for contraceptive devices and operations. The national government has become concerned over the problem and is now mandating collective support for personnel such as barefoot doctors (31, 57). Because the full responsibility system has taken root in the areas where birth planning has traditionally been least successful, its adverse impact is all the greater.



**In this Shanghai poster a barefoot doctor explains oral contraceptives to the happy mother of an only daughter, with her mother-in-law's apparent approval. The food, bicycle, sewing machine, and comfortable living quarters suggest that one-child families prosper.** (Courtesy of John Chao)

Local units have quickly responded with new measures to reconcile birth planning with the full responsibility system (55, 184, 366). In many areas the birth planning norms are now built into the housholds' annual production contracts. These contracts now stipulate that couples with one or more children will use an effective birth control method (sometimes even specifying a birth planning operation) and will have an abortion if contraception fails. Newlyweds without children pledge not to have a child before receiving a birth quota (112, 225, 244, 267, 366). When a pregnant woman refuses to have an abortion or has a child in violation of the contract, her family's farm plot can be taken away and other types of economic sanctions applied (30, 55, 267). Also, local cadres are being put under a new "cadre job responsibility" system as a part of these changes. The cadres' annual bonuses, which form up to 25 percent of their annual income, are dependent on their units' birth planning performance as well as on grain production and general economic prosperity (30, 267). The cadres must fulfill both grain and population targets to be eligible for the bonus. Because of these adaptations, the full responsibility system has had no effect on birth planning efforts in certain provinces. The most successful of the local innovations probably will be designated models for other rural areas (365), and successful adaptations to the new conditions will diffuse throughout the country.

## DEMOGRAPHIC PROJECTIONS

Since the People's Republic of China contains more than one-fifth of the world's population, any projections of global population growth must take account of demographic developments in China. Thus the temptation to prepare computer-simulated projections of Chinese population growth is difficult for observers of the Chinese scene to resist. To date projections have been prepared by the United Nations Department of International Economic and Social Affairs, the World Bank, the US Bureau of the Census, a number of US demographers, and a group of Chinese demographers. In general, the projections of the Chinese and of several US demographers are the lowest, while those of the US Bureau of the Census are the highest. Nevertheless, there is such variation both in assumptions about China's current population and in speculations and assumptions about future results of birth planning efforts

### Table 13. Population Projections for the People's Republic of China

| Author, Date & Ref. No. | Base Population for Projection (in Millions) and Year | Low, Middle, or High Projection | Fertility or Population Growth Assumption | Population in 2000 (in Millions) | Year of Peak Population | Size of Peak Population (in Millions) |
|---|---|---|---|---|---|---|
| **Chen 1978** (120) | 1,007 in 1978 | High | One-child certificate rate of 50% reached in 1982, sustained thereafter | 1,189 | ~2010 | ~1,200 |
| | | Middle | One-child certificate rate of 80% reached in 1982, sustained thereafter | 1,149 | ~2008 | ~1,160 |
| | 977 in 1978 | Low | One-child certificate rate of 50% reached in 1982, sustained thereafter | 1,125 | ~2005 | ~1,128 |
| | | Low | One-child certificate rate of 80% reached in 1982, sustained thereafter | 1,096 | 2000 | 1,096 |
| **Chen & Tyler 1981** (113) | 971 in 1980 | High | 3 children per family as of 1980, constant thereafter | 1,358 | Continuous growth | Continuous growth |
| | | Middle | 2 children per family as of 1980, constant thereafter | 1,185 | 2035 | 1,390 |
| | | Low | 1 child per family as of 1980, constant thereafter | 1,006 | 2000 | 1,006 |
| **Coale 1981** (157) | 910 in 1975 | High | CBR = 24.6 in 1975, declines to 16.0 in 1985. Thereafter annual number of births constant at 1985 level. | 1,148 | 2025 | 1,253 |
| | | Medium | CBR = 24.6 in 1975, declines to 16.0 in 1985. TFR declines to 1.7 in 1990, remains constant through 2020, then rises linearly to 1.9 in 2040. | 1,151 | 2020 | 1,220 |
| | | Low | CBR = 24.6 in 1975, declining to 19.0 in 1980. Natural increase rate = 0.5% in 1985, declining to 0.0% in 2000. Thereafter annual number of births constant at 2000 level. | 1,059 | 2000 | 1,059 |
| **Song et al. 1980** (372) | 970 in 1980 | High | TFR = 2.3 (1978 rate), constant thereafter | 1,282 | | |
| | | High | TFR declines from 2.3 in 1978 to 2.0 in 1980, constant thereafter | 1,217 | 2052 | 1,500 |
| | | Middle | TFR declines from 2.3 in 1978 to 1.5 in 1980, constant thereafter | 1,125 | 2027 | 1,200 |
| | | Low | TFR declines from 2.3 in 1978 to 1.0 in 1985, constant thereafter | 1,050 | 2004 | 1,054 |
| **Tsui 1979** (393) | 897 in 1975 | | TFR declines from 3.2 in 1975 to 1.9 in 2000 | 1,131 | | |
| **UN Department of International Economic and Social Affairs 1978** (399) | 895 in 1975 | High | Annual growth rate declines from 1.45% (CBR = 23.2) in 1975–80 to 1.06% (CBR = 17.4) in 1995–2000 | 1,228 | | |
| | | Middle | Annual growth rate declines from 1.33% (CBR = 22.1) in 1975–80 to 0.97% (CBR = 17.4) in 1995–2000 | 1,190 | | |
| | | Low | Annual growth rate declines from 1.22% (CBR = 21.2) in 1975–80 to 0.73% (CBR = 15.4) in 1995–2000 | 1,132 | | |
| **US Bureau of the Census 1979** (404) | 968 in 1975 | High | TFR declines from 5.2 in 1975 to 3.1 in 1985, constant thereafter | 1,488 | | |
| | 943 in 1975 | Middle | TFR declines from 4.1 in 1975 to 2.6 in 1985, constant thereafter | 1,380 | | |
| | 915 in 1975 | Low | TFR declines from 3.1 in 1975 to 2.1 in 1985, constant thereafter | 1,255 | | |
| **World Bank 1981** (435) | 977 in 1980 | | TFR reaches replacement level in 2005 but population growth continues due to age structure | 1,239 | 2105 | 1,565 |

TFR = total fertility rate CBR = crude birthrate that no projection made at this time is likely to be perfectly accurate. Rather, a set of projections should be used to outline a range of possibilities for the future and not to predict a single outcome.

The initial problem in making demographic projections for China is the lack of data about the current size and age structure of the population. Some demographers follow the official figures released by the PRC, while others prefer to generate their own estimates based on past census totals and assumptions about the decline in fertility and mortality since these censuses. In the projections listed in Table 13, for example, the 1975 base population size varies from 895 million in the United Nations estimates (399) to 968 million in the US Bureau of the Census high variant (404).

Next, assumptions must be made about future vital rates, especially birth and fertility rates. This requires, in effect, a prediction of the probable duration and success of the one-child campaign. The projections reported in Table 13 are based on assumptions ranging from one child per family by 1980 (113) to a total fertility rate (TFR) of 3.1 in 1985 (404). Some of these assumptions are not intended as predictions of actual fertility in China but instead were chosen to illustrate the differing impacts of various assumptions.

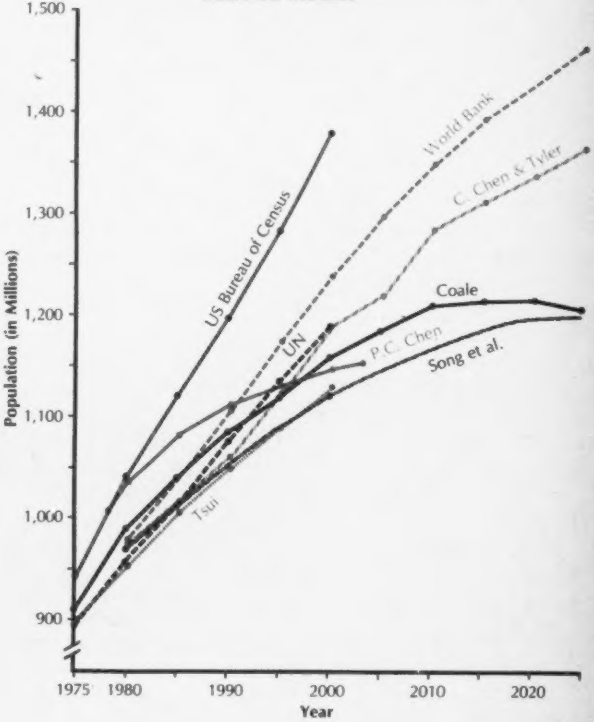
The differences in the demographers' assumptions about population size and age distribution in the base year and about future fertility levels lead to considerable differences in projected population in 2000. Of middle-range projections, the highest, by the US Bureau of the Census, is 1.380 billion (404), while the lowest, by the Chinese demographers, is 1.125 billion (372). This difference of 255 million people is larger than the population of any nation in the world except China, India, and the USSR. Most middle-range projections cluster between 1.1 and 1.19 billion (see Figure 4). The figure of 1.2 billion is now cited by Chinese officials as their target for the year 2000 (115). One important conclusion to be drawn from these differences is that the birth planning program has the potential to affect population growth in the PRC dramatically in the future as it has in the past decade.

In addition to preparing population projections, Chinese population scientists have been looking at factors that might help to determine optimal population size for the PRC. Taking into account food and nutrition, supplies of fresh water, other resources, the rate of economic development, and ecological equilibrium (328, 370), they have developed two population projections that fall within the optimal range of 650 to 700 million. In the ideal projection, the total fertility rate would be reduced to 1.0 by 1985. After the year 2000 it would rise to 2.16, so that China's population would stabilize at 700 million in 2070. Recognizing, however, that a TFR of 1.0 by 1985 is not demographically realistic, they proposed an alternative: total fertility would be reduced to 1.5 by 1990 and allowed to rise to 2.14 after 2025. In that case China's population would decline to 700 million and stabilize at that level by the year 2100—after reaching a maximum of 1.2 billion (371). This proposal to reduce the population of the PRC below its present level is unprecedented. It may reflect the urgent desire of the planners and the economists to improve China's economic situation rather than a political assessment of what is possible. Chinese political leaders are concentrating on the events of the next two decades and the problem of stabilizing rather than diminishing the total population of the PRC. Optimum population size is not an official concern at least for the time being.

## Age Structure

If the one-child campaign is even partially successful, there will be a dramatic change in the age structure of the PRC. For example, if family size drops sharply, eventually the labor force (ages 15 to 64) will shrink, while the number of aged dependents will grow. According to projections by Charles Chen and Carl Tyler, if all families have one child, the 1980 dependency ratio of 71 dependents for every 100 in the labor force would decline sharply to a low of 30 by the year 2000 and then increase to 77 by 2040. The age composition of the dependents would change radically, from over 80 percent children to over 80 percent elderly (113). Ansley Coale has projected that, if the PRC reaches ZPG by the year 2000, by 2035 about one-quarter of the entire population will be over age 65 (157). This compares with 10 to 15 percent in developed countries today, where pension funding already represents a large portion of government expenditures (418). This severe imbalance in the age structure, along with its long-term fluctuation, will create difficult socioeconomic problems, especially in allocating resources among the various age groups (113, 157). Whether to build schools or old age homes, whether

**Figure 4. Middle-Range Population Projections for the People's Republic of China, 1975–2025, Selected Studies**



| | Author & Reference Number | Estimated 1982 Population (in Millions) |
|---|---|---|
| ——— | P.C. Chen (120) | 1,054 |
| ┈┈┈ | C. Chen & Taylor (113) | 990 |
| ━━━ | Coale (157) | 1,010 |
| ——— | Song et al. (Chinese group)* (372) | 987 |
| ┈┈┈ | Tsui (393) | 975 |
| - - - | UN Dept. of International Economic & Social Affairs (399) | 980 |
| ——— | US Bureau of the Census (404) | 1,073 |
| - - - | World Bank (435) | 1,003 |

*Curve interpolated by Population Information Program on the basis of three plot points from Song et al.

to train teachers or health personnel, and how to retrain those whose skills no longer fill demographic needs will become major issues.

Critics of the one-child campaign within China have warned of future labor shortages and an increasing dependency ratio. In major policy statements Chinese officials have responded to these warnings, contending that: (1) the absolute size of the work force will continue to increase over the next three or four decades, (2) the dependency ratio will not become a problem until the year 2020, (3) the one-child policy will be terminated by 2010, before the age structure becomes too imbalanced, and (4) the government will institute better retirement and social welfare systems for the elderly as they are needed (32, 174, 428). Nevertheless, Chinese demographer Lin Fu de recently recommended a more gradual and limited one-child program in order to keep the age composition of the population more balanced. He proposed that fertility goals be set at an average of 1.5 to 1.6 children per couple for the period 1985 to 2025 and allowed to rise to 2.1, or replacement level, thereafter (291). Lin's recommendation is indicative of an increasing awareness in China of the problems of age structure. PRC officials also have expressed interest in learning about social welfare systems for the elderly in developed nations in order to prepare for their own future.

## UNFPA AID TO CHINA

Under a September 1980 agreement, the United Nations Fund for Population Activities (UNFPA) will provide $50 million (US) over a 4-year period to assist China in achieving the population targets of its "four modernizations" policy. The PRC government is matching the UNFPA money with $143 million. Six areas receive funding:

1. the 1982 nationwide census (see box, J-596),
2. contraceptive production and packaging,
3. human reproduction and birth planning research,
4. population information, education, and communication,
5. demographic training and research,
6. maternal and child health/birth planning services (67, 320).

Various organizations, including the United Nations Economic, Social, and Cultural Organization (UNESCO), the World Health Organization (WHO), and the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), have been named as executing agencies.

Some of UNFPA assistance will go to the establishment of training facilities in the PRC to enable the country to meet its needs for many kinds of professionals. Among the Chinese personnel and the training they will receive are:

- birth planning workers—task-oriented training,
- physicians—postgraduate training in family planning and maternal and child health care,
- engineers and technicians—improvements in contraceptive production, especially quality control and safety precautions for workers in steroid factories,
- demographers and social scientists—research and analytical methods (281, 320).

New factories will produce some 1.5 million plastic and copper IUDs to supplement China's annual production of 12 million stainless steel devices. They will also manufacture lubricated, transparent condoms in sealed foil packs that may be more acceptable to users than the opaque and unlubricated condoms currently available. They will produce bulk steroids and fill ampoules, thus tripling the annual output of injectables from 10 to 30 million doses (8). UNFPA funds also will establish a population information center to collect, translate, and disseminate foreign and Chinese scientific materials in population-related fields (320). New audiovisual equipment in Beijing and various provincial centers will strengthen government publicity and education efforts (281).

## PROGRAM IMPLICATIONS

China may offer some important lessons in the family planning field, but would-be imitators must be cautious. On one hand, some conditions in the PRC are similar to those in other developing countries: incomes are low, most of the population is rural, and trained personnel are scarce. On the other hand, some aspects of the Chinese situation would be difficult to duplicate elsewhere, and the Chinese themselves insist that birth control efforts must be closely tailored to local circumstances. The commitment of Chinese national leaders to health care and birth planning, their authority over all levels of government, and the lack of any significant opposition groups are unique. Also, birth planning activities are linked to the revolutionary restructuring of Chinese economic and social institutions, particularly the roles of women, the family, and various work units.

Nevertheless, there are at least three areas where the Chinese program can be instructive to other family planning programs. These include (1) strong information and education programs; (2) widespread, community-based availability of a broad range of family planning methods; and (3) sharing the responsibility for family planning and related health services between national and local governments.

### Information and Persuasion

Although the possibility of coercion may sometimes lurk in the background, the main thrust of the Chinese program is to encourage understanding and voluntary compliance with the government's recommended reproductive norms. This requires well-designed and pervasive campaigns that will convince a large portion of the population, if not all. The strengths of the Chinese information and motivation campaigns are:

- the content of messages is relevant to and easily understood by the people;
- messages are directed to everyone with influence on reproductive decisions, including young men and women, the older generation, and even children in school;
- messages are constantly repeated through many authoritative channels;
- the media are chosen to suit the people's preferences and prejudices;
- local leaders are expected to practice what they preach;

- all officials below the national level are held accountable for successes or failures in birth planning; rewards and punishments are meted out accordingly;
- positive incentives reward individuals who conform to national guidelines, with immediate benefits such as extra vacation as well as the promise of future gains for their children;
- peer pressure, including group meetings, reinforce information and persuasion (120).

All of these features are possible in other countries with population/family planning programs, and in fact some are already being used in many Asian countries.

Another major factor that supports birth planning educational efforts is the willingness of Chinese leaders to alter existing socioeconomic institutions and to create new ones that reinforce small family norms. Child care facilities keep women in the labor force, allowing them a role outside the family. Pension systems and old age homes reduce the economic dependence of aged parents on their children and meet the needs of those without children (287). Laws giving only daughters job preference and allowing them to carry on the family name may help to counteract the traditional preference for sons. In this fashion the government is trying systematically to eliminate the conditions that used to make large families desirable. For some developing countries such comprehensive changes would be difficult in the short run. Nevertheless, changes in this direction are now beginning to take place in many Asian countries where leaders perceive how rapid population growth can frustrate national economic development.

### Accessibility

Once Chinese couples have accepted the basic reproductive norms of later marriage and one- or two-child families, personnel and supplies to help them are close at hand. Contraceptives are delivered at home or at work, and even birth planning operations—IUD insertions, sterilizations, and abortions—are performed only a short distance away. Most of the birth control methods known in other countries—including abortion—are legal and accessible in China. Some other methods, not used elsewhere, such as visiting pills and gossypol, are also being employed or tested (see pp. J-590–595). In short, few programs anywhere in the world provide the array of methods found in China or offer them in ways that are so convenient to the user. Services are available at no charge and with considerable freedom of choice among methods.

### Shared Responsibilities

In order to maximize cooperation with other local units and to minimize the financial burden on the central government, the birth planning program relies heavily on existing infrastructure, uses many part-time and paramedical workers, and shares costs with local administrative units and employers (120). This form of organization economizes on the use of central resources, yet because of the high national priority attached to birth planning, local units are not allowed to neglect their responsibilities.

The Chinese birth planning program is well integrated with the health care system, and both emphasize self-reliance. In

YOU'D BETTER HAVE ONE CHILD ONLY
只生一个孩子好

**To influence the large number of young people now reaching reproductive age, publicity for the one-child campaign pervades Chinese life. Bicyclists in Chengdu, Sichuan province, pass a billboard proclaiming, "You'd better have one child only."** (Courtesy of Stewart E. Fraser) rural areas, local welfare funds, dues to the brigade cooperative medical fund, user fees, and collective income pay for the day-to-day operation of the birth planning delivery system, salary costs, and one-child incentives. Urban employing units provide similar support in the form of clinics, health insurance, and paid leave for birth planning operations. The state's contribution includes free contraceptives, reimbursement for the costs of birth planning operations, and subsidies for professional training and hospital equipment, and salary support for the full-time birth planning workers at the commune and higher levels.

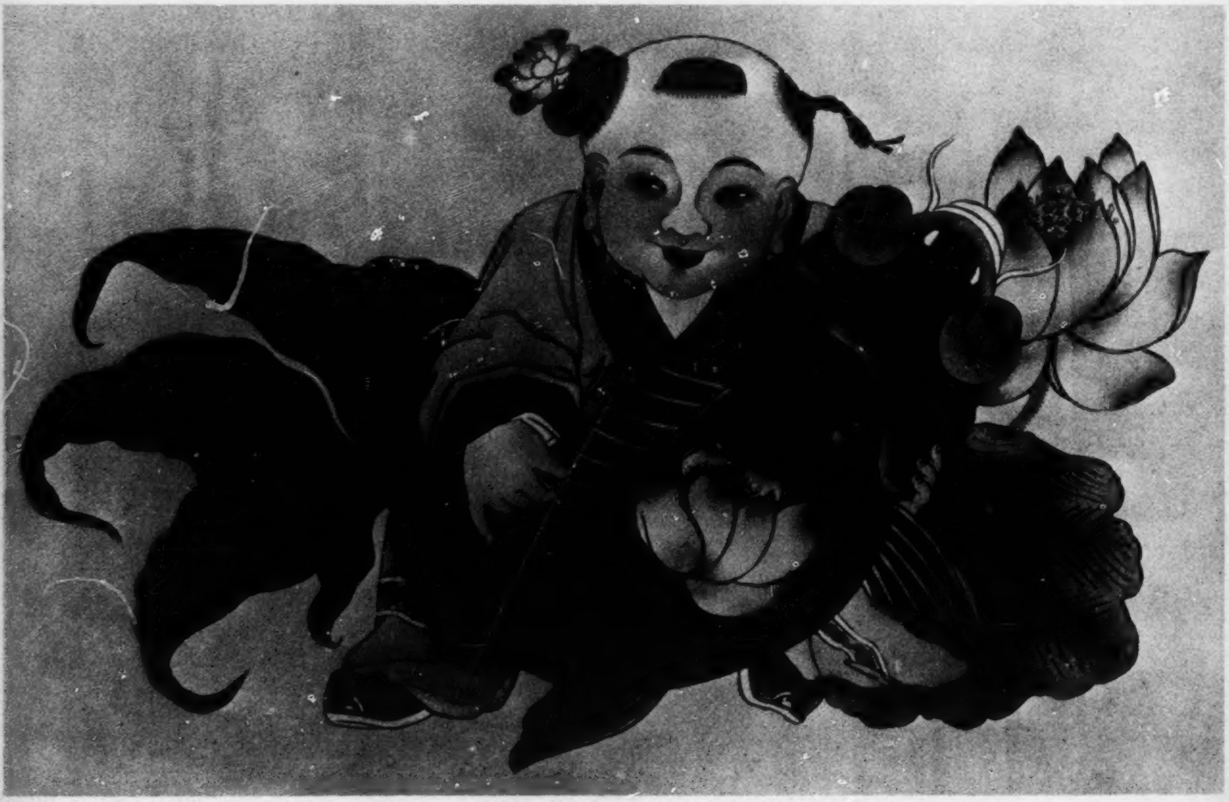
Overhead expenses are reduced by using the existing political, economic, and social organizations to promote and operate birth planning activities. For example, factories and agricultural cooperatives provide family planning services. Health care units take responsibility for the delivery of contraceptive services, and women's groups coordinate birth planning propaganda.

Many other developing countries, like China, face the problem of making family planning services widely available when trained medical personnel are scarce. One solution has been community-based distribution (CBD) programs, in which village leaders or other nonmedical distributors provide some contraceptive supplies to those living nearby (93, 273, 407). These programs were originally funded by private agencies, but now, as in China, many national programs place increasing reliance on paramedical workers (347, 353).

Birth planning policy is wholly determined on the national level, but local officials are responsible for program implementation. In this decentralized approach, local officials (1) feel free to choose whatever tactics best suit their area, (2) are required to practice what they preach concerning birth planning practices, and (3) receive full credit for a campaign's success or take full blame for its failure. Other Chinese techniques, such as community meetings to allocate birth quotas, place local birth planning decisions in the hands of each community. As a result residential and production units in China perceive that they are playing a crucial role in the birth planning process. This perception of local decision-making hides the reality of central control and fosters voluntary compliance.

In other countries where local political or other organizations are strong and provide genuine community leadership, as in Indonesia, for example, national priorities can be transmitted to these units and carried out effectively (126). Thus, family planning programs have been carried forward by the *banjars* (communities) in Bali, the village headman's staff in Java, and Mothers' Clubs in South Korea (81, 239, 284, 376). By contrast, where local government or other organizations are weak, as in Bangladesh (448), or where the national government is not committed to reducing fertility, programs may have less impact.

Thus, in its emphasis on extensive information and persuasion, on a wide range of accessible services, and on full utilization of existing facilities and nonmedical personnel, the Chinese birth planning program offers some useful examples for other programs. Basic to the success of these activities, however, is the strong commitment of national leadership, which has been translated into allocation of substantial resources and is pervasively communicated and implemented through a highly controlled social and political structure.



**This Beijing poster uses a traditional Chinese symbol for abundance—the fish—to show that birth planning ensures a surplus of food and clothing. The boy is well-fed and luxuriously clothed because he is an only child.** (Courtesy of John Chao)

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SPECIAL TOPICS

Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

# Population Education in the Schools

**Summary.** Formal population education is designed to teach children in school about basic population issues and, in many cases, to encourage them eventually to have smaller families. Some programs include specific units on human reproduction and family planning, while others do not. National population education programs began during the 1970s in about a dozen countries, mainly in Asia. These include Bangladesh, India, Indonesia, South Korea, Malaysia, the Philippines, Sierra Leone, Sri Lanka, Singapore, Thailand, Egypt, Tunisia, and El Salvador.

A strong case can be made for including an important contemporary issue like population in the school curriculum. Nevertheless, educational innovation is a difficult and long-term process. As a rule, it takes 5 to 10 years before new material can be fully incorporated in a school curriculum. Curriculum changes must be carefully planned, thousands of teachers trained, and appropriate materials prepared for classroom use. Moreover, differences of opinion over the need, acceptability, goals, content, methods, and other aspects of population education have held back programs in some countries. Where population education programs have been implemented, student knowledge of population issues increases, but it is not yet clear whether in-school education has a measurable impact on fertility-related attitudes or behavior.

### Rationale for Population or Family Life Education

Population education has been defined as

> an educational program which provides for a study of the population situation in the family, the community, nation and world with the purpose of developing in the students rational and responsible attitudes and behavior toward that situation. (250)

Why should such a program be part of formal schooling? Formal education should prepare the young for adult life by teaching relevant information and skills; it may help to build attitudes and values at an early age; it prepares individuals for roles as community and national leaders; and it supports national social and economic development. If the schools are to perform these vital roles fully, they should include population in the curriculum, since population and family life issues are an important aspect of many personal, community, and national decisions.

Population education takes various forms. The most comprehensive approach is through the government-operated primary and secondary school system. Usually population topics are incorporated in social studies, geography, home economics, science, and mathematics courses. The most extensive program is in the Philippines and includes all 12 grades. Since school dropout rates are high, programs restricted to secondary schools reach only a small percentage of the school-age population. Several countries, such as Indonesia and Sierra Leone, chose to start population education at the secondary level and phase in primary schools later.

Smaller-scale activities within the school system are underway in many other countries. They are often carried out by family planning associations or other private voluntary organizations, working in cooperation with the schools. Such activities range from sending speakers into classrooms, as in Mexico, or supplying teaching materials, as in Mauritius, to training teachers in a specific discipline, such as home economics or biology. Sometimes small projects have sparked the development of national programs. At the same time, of course, a great variety of vocational, extension, adult literacy, and out-of-school programs not covered in this report reach a generally older population.

### Government Population Policies

Where governments do not have policies to reduce growth or governments have changed, as in Sierra Leone and Sri Lanka, in-school programs tend to stress "population literacy"—that is, learning about population issues from different points of view so that students will be better able to make rational personal decisions. Where governments have explicit policies calling for a reduction in population growth, as in Indonesia, South Korea, the Philippines, and Singapore, in-school programs also seek to build support for government policy and to promote smaller families. As a UNESCO sourcebook on population education in Asia noted, "Population education is not meant to replace family planning, rather it is meant to be a supplementary and/or

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**This issue of Population Reports was prepared by Jacqueline D. Sherris, Ph.D., with the assistance of Wayne F. Quillin**, on the basis of published and unpublished materials, correspondence, and interviews. Comments and additional material are welcome.

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Phyllis T. Piotrow, Ph D., Director; Walter Stender, Associate Director; Ward Rinehart, Editor.

complementary program'' (226). Material about human reproduction and family planning is included in population education in some Asian and Latin American countries, usually as part of ''family life education.'' These topics are not included in other countries, such as Bangladesh, Indonesia, Malaysia, and Sri Lanka, because of anticipated religious, ethnic, or political opposition.

National population education programs are usually administered through a unit in the ministry of education. To be most effective, these units need to coordinate population education activities not only throughout the formal school system but also with community leaders, other population and family planning information programs, national or regional academic testing bodies, private schools and universities, and national and international funding sources. As with any program, continuity of leadership and high-level support are essential to success. (See Recommendations, p. M-230.)

In some developing countries population education has been linked with educational reform. Reform means introducing new subject matter relevant to modern life and encouraging new teaching methods that stimulate more student participation. On one hand, population issues lend themselves readily to this approach. On the other hand, teachers who are accustomed to giving lectures and calling on students to recite memorized material may find it difficult to guide class discussion on a new, complex, and possibly controversial subject.

### Role of Teachers Crucial

Success in implementing a population education program depends on how well teachers are trained and supported in introducing the new subject. For a national program this is a massive task. Thousands of teachers now in classrooms need training and continued guidance. If population education is to become a standard part of the curriculum, pre-service training for new teachers also is required.

How can so many classroom teachers be trained? Face-to-face training is preferable, but it is time-consuming and expensive. Those who train the teachers must be trained first. Widely dispersed teachers have to come to training centers, and during the school year substitutes may be necessary in the classroom. At best, most programs can manage a 3- to 5-day training course, but in both South Korea and the Philippines teachers found that this was not enough. Independent self-learning projects and correspondence courses, sometimes tried as alternatives, are not always effective. In surveys teachers cite insufficient training and an already overcrowded curriculum as the major impediments to population education.

Furthermore, teachers need textbooks, lesson plans, model lessons, charts, and, if possible, student workbooks. Because classrooms are crowded and teachers overworked, teachers need simple, practical materials, linked to local issues, that can be used without extra work on their part. In places as diverse as Baltimore in the US and the Philippines, teaching materials have proved most successful when teachers helped to prepare them.

The most efficient way to incorporate population topics into teaching materials is during a comprehensive curriculum revision. This was done in Indonesia, Nepal, Sierra Leone, and Sri Lanka. Such revisions usually take place no more than once or twice a decade, however. Another effective way to see that population topics are really taught in class is to include questions about population on standardized national or regional exams.

### Implementation

''The ultimate goal of a population education project is to become an institutionalized, integral part of the educational system,'' according to T. S. Mehta, an Indian educator who helped to develop guidelines to include population education in World Bank loans. At that point, the additional effort and cost of maintaining the program should be minimal, since materials are already prepared and teachers trained. South Korea, after about eight years of assistance, no longer receives external funds for in-school population education. There are, however, no general guidelines to indicate how long it should take or how much it should cost to implement a population education program in the schools.

In most countries implementation has been slow. Funding from the United States Agency for International Development, the United Nations Fund for Population Activities, and the World Bank has helped to stimulate programs, but long-term national effort is necessary to institutionalize a national program. Except in a few countries, most of the effort to date has focused on curriculum development and pilot projects, with full implementation still ahead. In many countries program leaders have moved to new jobs, and initial plans have been delayed or changed in scope. Differences of opinion may persist between family planning officials who want to see a measurable impact on fertility and educators who prefer to stress teaching basic skills and subjects rather than trying to convey a message such as the need for smaller families.

Overall, the field of population education is a challenging one—difficult because it involves large and cumbersome educational systems that are underfunded and overburdened; frustrating because it requires close coordination among many different groups without producing an easily identified result; but critically important because it has the potential to inform and influence the younger generation on a subject of vital personal and global importance. **End of Editors' Summary.**

## BACKGROUND

What is population education? A much used definition, proposed at a 1970 workshop in Asia sponsored by the United Nations Educational, Scientific, and Cultural Organization (UNESCO), states:

> Population education is an educational program which provides for a study of the population situation in the family, the community, nation and world with the purpose of developing in the students rational and responsible attitudes and behavior toward that situation. (250)

The 1981 Conference of African Parliamentarians on Population and Development devoted considerable attention to population education. The Conference defined population education as

> an educational program which helps individuals and groups . . . to define for themselves the nature of the problems involved in demographic processes . . . and to determine the means which society as a whole, and they themselves as individuals and/or groups, could use in order to react to those processes and influence them with a view to improving the quality of life, both present and future. (172)

African approaches to population education usually emphasize cultural diversity, "education for development," environmental issues, and family life education for girls (172, 248). Acquiring knowledge is stressed more than changing attitudes or behavior.

A Latin American seminar defined population education as a

> multidisciplinary educational effort that shows the factors which influence the qualitative and quantitative characteristics of the human population and that contributes to the preparation of the individual in the areas of sexual education, family life education, civics, population awareness and environmental education. . . . (280)

In a number of Latin American countries population education focuses more on the individual and family life than on demographic issues.

The nature of population education, including both the content and goals of in-school programs, varies widely. One observer concludes that "population education will be what population educators in each locale define it to be" (31). In many respects population education will depend on overall national policies and the degree of government and community concern over population issues.

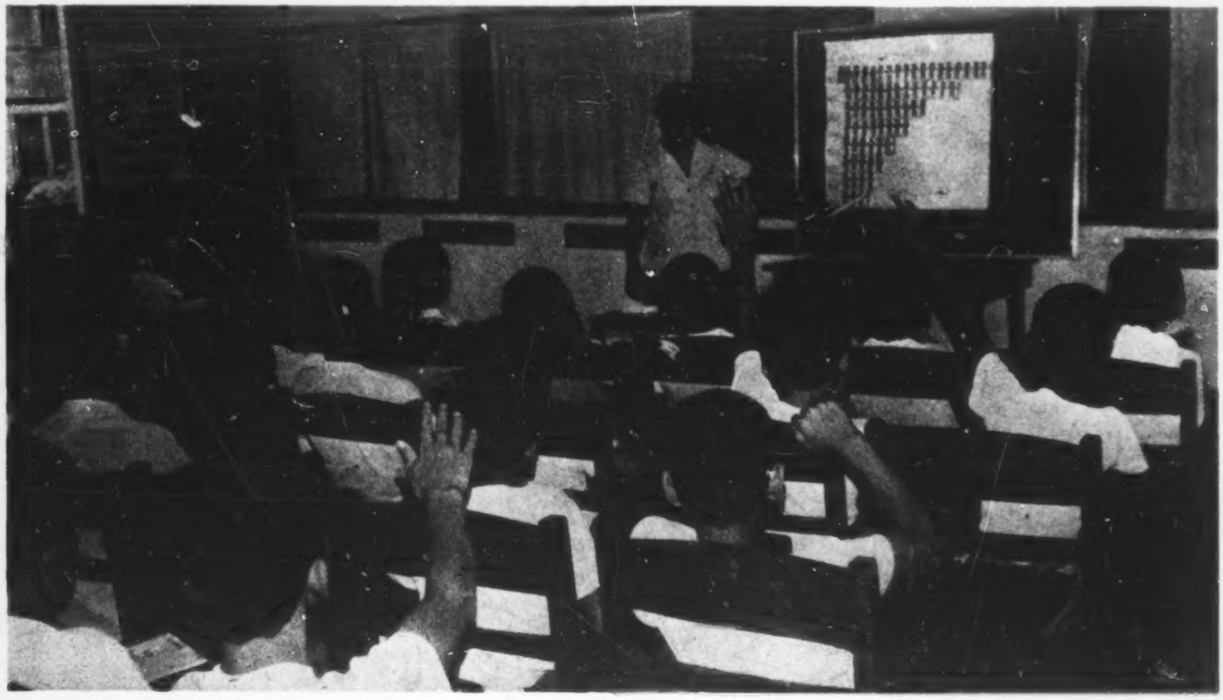
### Current Programs

The first proposals to include population issues in school curricula were made as early as the 1930s by the Population Commission of Sweden (149) and the US National Education Association (113). Concern about *declining* population growth rates in developed countries motivated these proposals.

By the late 1960s rapid population growth had revived interest in population education. Many governments, especially in developing countries, were adopting national policies either to reduce population growth or to provide family planning services as an integral part of health and development programs. As a result, more attention turned to the role of the school system in teaching children about population issues and influencing their attitudes about family size at an early and formative age. In 1974 the World Population Plan of Action declared,

> Educational institutions in all countries should be encouraged to expand their curricula to include a study of population dynamics and policies, including, where appropriate, family life, responsible parenthood and the relation of population dynamics to socio-economic development and to international relations. (312)

Now almost a dozen national programs are reaching the schools, and many more are in planning stages. During the



**At least 40 percent of the people in most developing countries are under age 14 and spend some years in school. To take advantage of the opportunity to reach so many people, a number of countries have started population education programs in the schools. In the Philippines nearly all children attend primary school. Here third-grade math students study population growth.** (Philippine Population Education Program)

1970s a number of national programs were begun, mainly in Asia, with funds from the United Nations Fund for Population Activities (UNFPA), the World Bank, and the United States Agency for International Development (USAID) and often with technical assistance from UNESCO. Bangladesh, South Korea, Indonesia, Malaysia, the Philippines, Sri Lanka, and Thailand have received aid ranging from $500,000 (US) to over $1 million for 5- to 12-year programs. In other regions Tunisia, El Salvador, and Sierra Leone have started national population education programs. (See Table 1 and Table 2, pp. M-232–235.) During the 1980s India, Nepal, and China will undertake programs with UNFPA funding that ranges from about $500,000 each for China and Nepal to over $5 million for India—the largest single population education grant (see Tables 2 and 3, pp. M-232–237).

With or without outside funding, a number of private population and education organizations around the world have created local or small-scale activities to help teach school children about population. Their activities range from preparing materials for classroom use to sending speakers into the schools (see p. M-207). The activities of private family planning organizations and similar groups laid the groundwork for national government population education programs in a number of countries, including the Philippines and South Korea.

## Rationale

The rationale for teaching about population in schools is clear:

- The purpose of education is to prepare the young for adult life. This requires both presenting relevant information and teaching analytical processes and skills that can be broadly applied. Since population affects all aspects of modern life, important population issues and methods for analyzing population problems should be an integral part of in-school education (117, 331, 338).
- Education can also build the attitudes and values that shape individual and social life (349). Where the environment, responsible parenthood, and other population-related issues are important national concerns, they should be addressed in the school curriculum.
- Family planning service programs often reach women only after they have had several children. Population education, especially when family life and sex education are included, can introduce and encourage the idea of responsible parenthood and/or smaller families to both males and females (75, 192), and it can do so before reproduction begins.
- Schools prepare national leaders. Since those who have attended school often are influential in their communities, the schools should provide a basic background in population that would be useful for future leaders and officials.
- All countries have organized school systems with facilities and personnel in place. At least 40 percent of the population in most developing countries is under age 14 and attends school for some years. These children can be introduced to population and/or family life issues through the school system without need for new organizations or institutions.
- Changes in traditional family and community life, accelerated by migration to the cities and exposure to mass media, have diminished parental authority and enhanced the influence of the schools and peer groups on children (245).
- Finally, formal education legitimates society's concern with the subjects being taught (337). Thus, omitting population from the school curriculum might suggest that the issue has low national priority, even if the government supports family planning or other population programs.

**On a field trip students see for themselves how population size affects resource use. In some countries population education has been a vehicle for educational reform. Innovations such as field trips and discussion may replace lectures and recitation.** (UNESCO)

## Population Education and Educational Reform

Another argument made for population education is that such programs contribute to educational reform. In many developing countries the movement for educational reform gained momentum in the 1970s. Reformers wanted to move away from educational systems established by colonial governments (191) or organized solely along traditional or religious lines (198). They wanted, among other things, to add socially relevant subjects and practical vocational training to the curriculum instead of concentrating entirely on traditional subjects such as mathematics, history, and language (191, 356). They wanted to decentralize school systems so that schools in rural areas could better meet the needs of their students (119, 142, 198) and to encourage more girls to enroll and stay in school (25). Also, they hoped to introduce new teaching methods that stimulate active student participation in place of traditional "read-and-recite" techniques—lecturing by teachers and memorizing by students (64, 246).

For advocates of educational reform, population education has offered an opportunity to change both curricular content and teaching methods (89, 225, 246). Population topics are socially relevant. They can easily be adapted to new teaching methods such as "inquiry learning" and "values clarification." Inquiry learning calls for students to discover basic patterns or concepts from facts provided by classroom materials (18). For instance, using this approach, census data can stimulate a discussion of fertility, family size, and socioeconomic problems. Values clarification seeks to make students aware of their own attitudes and opinions on an issue (165, 329, 339). For instance, students may be asked how they feel about two statements: "Freedom of choice for each individual—having children is a personal matter" and "One more won't make any difference" (548). Both methods encourage student participation and may develop analytical and decision-making abilities (54, 89). In Egypt, for example, the use of these new techniques in population education has aroused widespread interest among educators in their use for other subjects (147) (see box, p. M-218).

Some observers, however, question whether population education should be linked so closely to educational reform. Using

## Table 1. Major Characteristics of Selected Established In-School Population Education Programs

| Region, Country, Date of Program Initiation, & Ref. No. | Government Population Policy & Year Adopted[1] | Administering Agency | Curriculum | | | Teacher Training | | Materials Developed | Program Evaluation[2] |
|---|---|---|---|---|---|---|---|---|---|
| | | | Content Emphasis | Grade Levels | Subjects Used | In-Service | Pre-Service | | |
| **ASIA & PACIFIC** | | | | | | | | | |
| **Bangladesh 1976** (56, 134, 266, 278, 289) | A 1971 | Population Education Program in Ministry of Education | Population trends and effects, population and development | 4–12 | Home economics, language, mathematics, natural science, social science, social welfare, and vocational and technical education | Training sessions by district population education officers, administrators, and trainers | Partially introduced in primary and secondary teacher training curricula | Teachers' manual in pilot stage | UNFPA needs assessment, 1978 (290); evaluation of change in student knowledge, 1980 (363); review of teacher training progress, 1980 (362); UNESCO evaluation of program progress, 1980 (208); tripartite review, 1981 (189). |
| **Indonesia 1974** (56, 72, 75, 133, 134, 219, 257, 266) | A 1968 | National Population Education Project in Ministry of Education and Culture. Coordination by BKKBN. | Population trends and effects, government policies | 4–6 | Natural science, religion, social science | One-day to one-month training courses for some master teachers[3] | Partially introduced in some training institutions for secondary school teachers | Student textbooks, teachers' manuals | Some evaluation of training and materials, 1979 (75); UNFPA needs assessment, 1979 (294); tripartite review, 1981. |
| | | | | 7–12 | Geography, natural science, religion, sports and health | | | | |
| **Korea, Rep. of 1974** (106, 219, 246, 257, 266, 313) | A 1961 | Central Office of Population Education in Ministry of Education | Population trends and effects, family life, human reproduction, family planning, government policies | 4–12 | Geography, home economics, physical education, science, social studies | 3- and 5-day courses for secondary school teachers, training booklet for primary school teachers | Population course in some universities and training colleges | Teachers' manual, student workbook, reference and resource texts, visual aids | Evaluation of curriculum, 1974, 1975, 1976 (106); UNFPA needs assessment, 1980 (313); tripartite review, 1981. |
| **Malaysia 1973** (116, 118, 134, 219, 257, 266) | A 1966 | Population Education Program in Curriculum Development Center of Ministry of Education | Population trends and effects, environment, government policies | 4–9 | Civics, general science, geography, health, history, language | Regular in-service training for some master teachers[3], SLEMs in pilot stage | Integrated into health curriculum of training institute | Teachers' manuals, teacher training materials | UNFPA needs assessment, 1979 (301); tripartite review, 1981. |
| | | | | 4–6 | Mathematics | | | | |
| | | | | 7–9 | Home science | | | | |
| **Philippines 1972** (246, 266) | A 1970 | Population Education Program in Department of Education and Culture | Population trends and effects, human reproduction, family planning, government policies | 1–10 | Health, mathematics, social studies | Week-long courses for primary and secondary level instructors, SLEMs for teachers unable to attend | One-semester course at many teacher training institutions | Student workbooks (limited distribution), teachers' manuals, teacher training modules and course guides | Changes in student knowledge and attitudes assessed, 1970–1972 (17); pilot test of curricula, 1973–1974 (17); UNFPA needs assessment, 1979 (311). |
| | | | | 1–8 | Science | | | | |
| | | | | 5–10 | Home economics | | | | |

(Continued on next page)

**Table 1. continued**

| Region, Country, Date of Program Initiation, & Ref. No. | Government Population Policy & Year Adopted[1] | Administering Agency | Curriculum |  |  | Teacher Training |  | Materials Developed | Program Evaluation[2] |
|---|---|---|---|---|---|---|---|---|---|
|  |  |  | Content Emphasis | Grade Levels | Subjects Used | In-Service | Pre-Service |  |  |
| **Singapore 1973** (72, 86) | A 1965 | Singapore Family Planning and Population Board (SFPPB); Ministry of Education | Importance of small family | 5<br>1–6<br>10 | Education for living<br>Health<br>Course for low achievers | Informational seminars for teachers and principals | Lecture series in health education course | NA | NA |
| **Sri Lanka 1973** (20, 72, 257, 266, 277, 278) | A 1965 | Population Education Project in Curriculum Development Center of Ministry of Education | Population trends and effects | 6–9 | Health, language, mathematics, science, social studies | Training by master teachers as part of regular in-service program | 15-hour course in training colleges | Supplementary course guides, reference book for teachers, sourcebook | UNFPA needs assessment, 1980 (315); UNESCO survey of student knowledge and attitudes, 1981 (209). |
| **Thailand 1972** (138, 229, 266, 278, 319, 472) | A 1970 | Population Education Unit in Curriculum Development Center of Ministry of Education | Population trends and effects | 1–7<br>8–12 | Life experiences (family life and environment)<br>Social studies | 5-day course for some secondary teachers; some others oriented at in-service training. | One-semester course in training colleges | Teachers' manuals and course syllabi as part of general textbook revision | UNFPA needs assessment, 1979 (320) |
| **AFRICA & MIDDLE EAST** |  |  |  |  |  |  |  |  |  |
| **Sierra Leone 1977** (79, 114, 164, 314) | C[4] 1978 | Institute of Education of the University of Sierra Leone | Population trends and effects | 8–10 | Social studies | 1- to 2-week summer workshops | NA | Supplement to text for grade 8, new texts for grades 9 and 10 | Tripartite review, 1981 (164) |
| **Tunisia 1972** (241, 246) | A 1964 | Population Education Team in Ministry of Education (until 1975 in Ministry of Health) | Population trends and effects, family and religious values | 7–13 | All | 3- to 4-day seminars and workshops, one-day sessions on a theme or method | NA | Course outlines, audiovisual aids | UNFPA needs assessment, 1981 (324) |
| **LATIN AMERICA** |  |  |  |  |  |  |  |  |  |
| **El Salvador 1971** (246) | A 1974 | Family Education Program, 1971–73; Director of Adult Education, 1974–75; Director of Education Services, 1976–. | Family life, environment, population dynamics | 1–9<br>10–12 | All<br>Biology | Several teacher workshops | NA | Some teachers' manuals, educational games | UNFPA program progress mission, 1977 (213) |

Note: For information on funding of some of these programs, see Table 3, pp. M-235–237.

SLEM = Self-Learning Educational Module
NA = not available
BKKBN = National Family Planning Coordinating Board (Indonesia)

[1] National government population policy from Nortman & Hofstatter (161) except where otherwise noted
A = government policy is to reduce population growth rate
B = government supportive of family planning for nondemographic reasons
C = government policy either neutral or pronatalist

[2] Includes evaluation of program impact, tripartite reviews, preprogram assessments, and UNFPA needs assessment missions. Tripartite reviews are joint UNFPA, UNESCO, and host-country agency evaluations of how well a program is progressing towards its established goals. UNFPA needs assessments are 2-week visits by UNFPA staff and consultants to establish the current status and projected needs of all population programs, including population education.

[3] A master teacher is a teacher from a particular school responsible for training all teachers in that school (i.e., a peer trainer) or a teacher of a particular subject responsible for training all the teachers of that subject in the district or region.

[4] Source: UN (283)

population education to introduce new teaching techniques may confuse teachers trained in traditional methods and may divert the program from its main purpose—to teach about population. Both teachers and students may be unsure of what is expected of them. In Thailand, for example, where population education was the justification for a complete revision of the curriculum and of teaching methods, the information about population and family size that actually reaches the classroom is limited, according to recent observers (200, 231). Population education in Thailand includes such varied elements as discouraging prostitution and criticizing excessive ceremony.

### Challenges in Implementing Population Education

The importance of including population issues and analysis in formal education is clear, but practical questions arise in implementing any program. These questions can be considered in terms of the six elements of any population education program:

**Planning:** Is a comprehensive national program feasible? If not, what alternatives are available? What are the goals of the population education program? Should population education promote specific attitudes or behavior, or should it emphasize acquiring basic knowledge and analytical skills? What should be the content and emphasis of population education? Should information on human reproduction and family planning be included? Should population issues be taught in primary or secondary school or both?

**Administration:** How should programs be administered and funded? How can adequate coordination be maintained? Can standardized tests include questions on population?

**Curriculum Planning:** Should population topics be treated in separate courses or integrated with other subjects? What topics are appropriate for different grade levels? How can concepts be organized in logical sequence throughout the various subjects and grade levels?

**Teacher Training:** How can thousands of widely dispersed teachers be adequately trained to present new and complex material, often using unfamiliar teaching techniques? How can universities and other teacher training institutions be encouraged to prepare new teachers in the field of population education?

**Teaching Materials:** Who should prepare materials on population to be used in the classroom? What kind of training do materials developers need? How can materials be distributed to all teachers and classrooms? How can materials be adapted to different settings?

**Evaluation:** How should progress in population education be evaluated? To what extent have plans for population education actually been implemented in the classroom? To what extent do changes in students' knowledge, attitudes, or behavior occur as a result of population education in the schools? Is it possible to measure changes in behavior that can be attributed to population education?

These are questions policy-makers, educators, and funding agencies need to consider in undertaking population education programs. The role of school systems is crucial to national development, but carrying out any educational innovation is difficult. Moreover, unlike the impact of some health and population programs, the impact of population education in the schools is not easily measured or demonstrated.

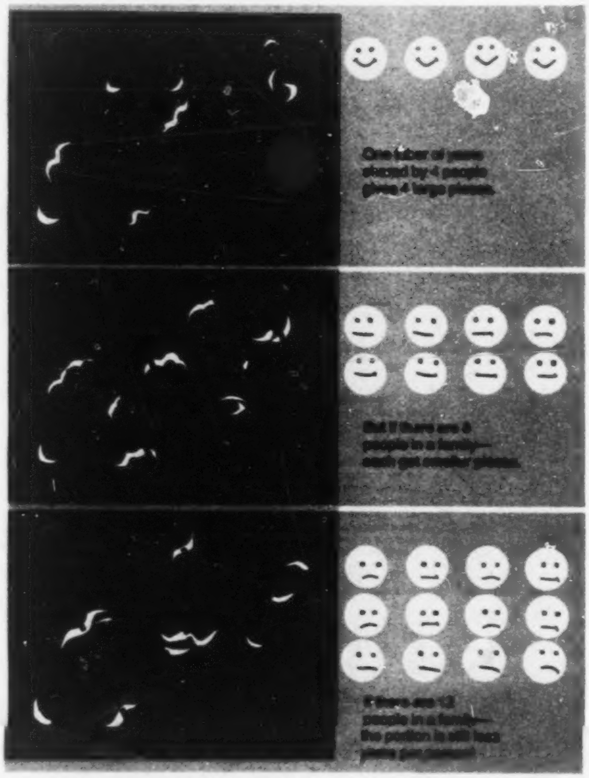
## PLANNING

The first step in any population education program is to decide on the type of program and program goals. The type of program depends on what is politically, financially, and organizationally feasible. Program goals largely reflect national population policies since some form of official approval is required to work in the schools. Then the content and grade levels to be included must be determined. Content reflects the demographic situation and concerns of the country as well as planners' perceptions of what is acceptable to government and community leaders. The grade levels to be reached—primary or secondary school—depend on various factors including school enrollment and available resources.

### Type of Program

Most of the programs discussed in this report are large-scale, nationally mandated ones. National programs usually are centrally controlled, functioning within the established educational hierarchy. The existing educational system bears most of the responsibility for planning and implementing the program. National programs have the authority to specify the priority for population education in the curriculum. They can integrate and coordinate population content with existing courses. And they have the potential to teach large numbers of students about population issues.

In many countries large-scale, national programs are not feasible because resources are not available, because the govern-


One tuber of yams [illegible] by 4 people gives 4 large pieces.
But if there are 8 people in a family— each get smaller pieces.
If there are 12 people in a family— the portion is still [illegible]

**Even physical objects can illustrate population concepts. This American Home Economics Association poster shows that portions of a yam are smaller when it must be divided among the members of a large family.** (American Home Economics Association)

# Population Education in the Philippines

The major goal of the Philippine population education program is to encourage lower fertility, but it has also had a major impact on strategies used to introduce new concepts into a traditional curriculum. In 1969, meetings with university presidents, initiated by the Family Planning Association of the Philippines with the help of the Ministry of Education, aroused interest in population education. Planning began in the early 1970s with curriculum development at private institutions and workshops. This led in 1972 to the establishment of a national program funded by UNFPA. The program seeks to encompass all grade levels and major school subjects. At present, the program is working to reach nongovernment schools (268). Although most primary school students attend public schools, about two-thirds of secondary school students attend private or vocational schools where population education is not taught (246). Nevertheless, the scope of the program is remarkable, particularly in light of the diversity of the Philippine population.

**Planning and administration** of the project are carried out through a Population Education Program (PEP) within the Ministry of Education. Long-range goals are: to reduce desired family size, to develop responsible decision-making skills, and to make education more relevant to national needs. Short-term goals are: to train teachers, to develop materials for use at all levels, and to assure the permanent inclusion of population concepts in the established curriculum. Three divisions of PEP—training, curriculum development, and research—were established to coordinate activities related to these goals.

Since students at all grade levels were to be taught population concepts, the first task in **curriculum planning** was to decide which concepts should be included in each subject at each grade level. The matrix on p. M-222 shows the concepts included in each subject at the primary school level. In both primary and secondary school grades, short subunits on population issues were added to social studies (545), health (543), science (546), mathematics (544), and home economics courses. Two problems became apparent during this process: (1) the overcrowding of existing curricula and (2) the difficulty of choosing appropriate courses and levels for controversial topics such as human reproduction and family planning (17, 19, 341). Since only half of all eligible students attend secondary schools (see Table 4, p. M-212), these topics had to be included at the primary level. Planners eventually decided to include such topics as "knowing the genital organs" and "changes at puberty" in the primary grades, whereas "the human reproductive process" and "methods of contraception" were included in secondary grades (246).

As in most programs, in-service **teacher training** has been the greatest challenge. PEP's 1972 goal was to train 186,000 primary school teachers and 15,600 secondary school teachers by 1978 (246). The strategy developed to meet this goal was a tiered scheme: division supervisors took a 5-week training course covering population concepts, human sexuality, population education goals, and innovative teaching methods. These supervisors were then grouped into supervisory-training teams (STTs), which were to hold one-week teacher training sessions in their districts (120, 471). Three years later, by the summer of 1975, fewer than one-third of the primary school teachers had been trained; secondary school teacher training had only just begun; and, of the original 410 supervisor-trainers, only 197 were still in the program (232). In light of these problems, two new teacher training strategies were developed—40-hour in-school sessions led by school administrators, and individualized training modules. Through this combination 208,000 primary and 40,000 secondary school teachers had been exposed to population education by 1978. This constituted 80 percent of all primary school teachers and 65 percent of all secondary school teachers (176). In addition to these in-service efforts, a 3-unit population education course (470) is offered, sometimes required, in teacher training institutions throughout the Philippines (56).

At the primary school level, teaching **materials** emphasize the impact of population trends on individuals and families. At the secondary school level, general population concepts and skills are emphasized. Materials include teachers' guides in both English and Pilipino (538–546), self-learning booklets for teachers (457–469), and a teacher training course guide (456). In a 1980 survey of 270 elementary school teachers, only about half thought that population education materials were adequate for their teaching needs (62). The survey and other field tests of materials also revealed that some materials were too complex (18, 19, 339, 340). In addition, teachers complained that lack of time made the introduction of new content and methods difficult (17, 62).

**Evaluations** have been undertaken by the PEP research section, some universities and colleges, and doctoral students. They include assessments of teaching materials and teacher training, site visits, and follow-up surveys in the schools (246) (see Evaluation, pp. M-224–231). One evaluation technique that has been useful in identifying difficulties encountered during implementation of population education is the "research utilization conference" (19). During these conferences, teachers, administrators, and researchers first read literature reviews of topics such as inclusion of human sexuality in the curriculum (341) and the effectiveness of discovery (inquiry) learning techniques (18). They then discuss how these reviews relate to actual classroom experiences. From these discussions, the following major needs had been identified by 1977:

- revised teacher training programs that address population content and new teaching techniques more thoroughly,
- additional teaching and reference materials on population issues and human sexuality,
- more efficient distribution of materials,
- more materials relevant to local conditions and in local language or dialects. (This is now being addressed by a "regionalization" project that seeks to adapt specific topics to different geographic areas (177).)
- consolidation with other subjects to reduce overlap and overcrowding (17).

Some of these needs will not be easily met, largely because the program is already underway on a national scale and the education hierarchy may not be flexible enough to deal efficiently with local or subject-specific needs.

ment or education ministry does not support population education, or because schools are locally controlled. Population education can still take place, however. As an alternative to national programs, and sometimes in addition, smaller programs may address a few issues or may be implemented in a small geographical area. Such programs often are operated by groups outside the schools, working with the cooperation of school officials. Although these programs are not comprehensive, they are relatively easy to implement, and they expose at least some children to important ideas. These smaller programs range from providing speakers for classrooms to training teachers of specific subjects.

In one type of small-scale activity, private family planning or other organizations make presentations in the schools about population and family planning. This requires the support of the school district but avoids the need for a large teacher-training program. An example of this technique is found in the state of Chihuahua, Mexico. Since 1974 the Centros Maternidad-Infantil y Planificación Familiar, headed by Guadelupe de la Vega, has been making 3-hour presentations on the importance of family planning to sixth-grade classes (57). Psychologists and a physician talk to the students, use audiovisual materials, and answer questions. In the United States local Planned Parenthood Associations or trained health educators make presentations to classes and to groups of teachers (178). While valid and useful, these types of activities may have limited impact, since students usually are exposed to population content for only a short time.

Some school systems without official programs use pamphlets or books about population that are prepared for students and teachers by other organizations. For instance, beginning in 1970, the Mauritius Family Planning Association (MFPA) distributed to all primary schools a booklet on population trends by the International Planned Parenthood Federation (IPPF). Entitled *Facing the Future: A Workbook for the Children of Mauritius* (514), it included an endorsement of the booklet by the prime minister. The workbook was simple yet comprehensive and could be used in class with little teacher input. In part because of these MFPA activities, the Mauritius Institute of Education now offers a course on population and family life education to interested teachers (166).

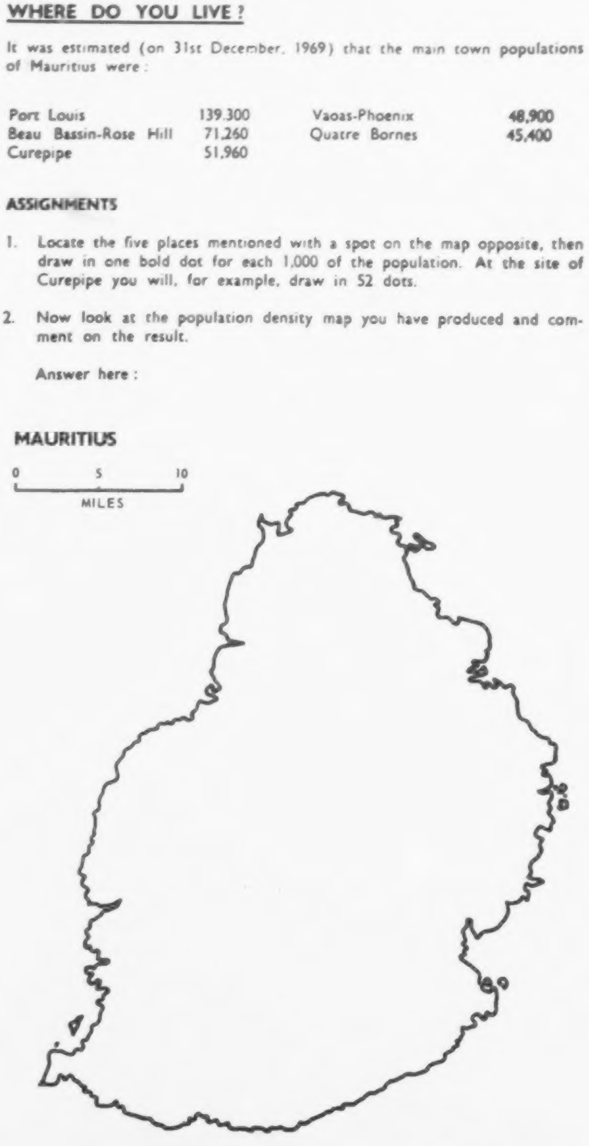
Population education also has been promoted through specific disciplines. Beginning in 1971 the American Home Economics Association (AHEA), with assistance from the US Agency for International Development (USAID), has helped home economists in 28 countries to integrate population and family planning information into their programs, including in-school programs (26, 143). For example, Jamaica received $50,000 (US) as "seed money" in 1972 (143). The project included updating home economics curricula in teacher training colleges and organizing workshops for home economics teachers.

Another example of introducing population education through a specific discipline is the Biological Sciences Curriculum Study in the US. This organization produces texts and other teaching materials for biology courses. Many of these now include discussions of human population changes and their environmental and social effects (146). Including population topics in standard texts is a particularly cost-effective way to introduce population education.

### Program Goals

All national population education programs have as stated goals to increase knowledge and understanding of population issues, especially as they relate to social and economic development within each country. Most programs also include as a goal to help students develop rational and responsible attitudes and behavior on population-related issues in personal, family, and community life (116, 246, 278, 289, 292, 295, 308, 312). But the extent to which these general objectives are spelled out in terms of specific lessons varies widely. It is sometimes not clear what the goals of a population education program really mean in the classroom.

In practice, the goals and, indeed, the very existence of population education programs depend on the overall population policies of the country. In Asia, for example, where many governments consider rapid population growth an obstacle to socioeconomic development, population education programs are usually designed to influence fertility. As was pointed out in the 1970 UNESCO workshop, "The reason for including popu-



**WHERE DO YOU LIVE ?**

It was estimated (on 31st December, 1969) that the main town populations of Mauritius were :

| | | | |
|---|---|---|---|
| Port Louis | 139.300 | Vaoas-Phoenix | 48,900 |
| Beau Bassin-Rose Hill | 71,260 | Quatre Bornes | 45,400 |
| Curepipe | 51,960 | | |

**ASSIGNMENTS**

1. Locate the five places mentioned with a spot on the map opposite, then draw in one bold dot for each 1,000 of the population. At the site of Curepipe you will, for example, draw in 52 dots.
2. Now look at the population density map you have produced and comment on the result.

Answer here :

**MAURITIUS**

**Many private voluntary organizations have supplied the schools with speakers or teaching materials on population. In Mauritius the International Planned Parenthood Federation and the Mauritius Family Planning Association prepared a student workbook that uses participatory exercises to teach concepts such as population density.**
Source: Hazelden, D. and Naik, R. Facing the future: a workbook for the children of Mauritius. Nairobi, Kenya, International Planned Parenthood Federation and Mauritius Family Planning Association, 1972. (514)

# Population Education in the Republic of Korea

The South Korean population education program evolved from the government's population policy, which in 1962 established the goal of reducing annual growth to 1.6 percent by the end of 1981 (161). In-school education was seen as a means to increase awareness of population growth and to change traditional values that contribute to high fertility (99). Using the education system to support government policies makes particular sense in Korea, where school attendance is high, ranging from 98 percent in grades 1 through 6 to 64 percent in grades 10 through 12 (244). Also, Korea is relatively homogeneous in culture, religion, and language. Studies in the early 1970s by the Central Educational Research Institute and the National Family Planning Center indicated that an organized population education program would be accepted by most communities (34, 100).

In 1974 the Korean government, the Ministry of Education, and UNFPA announced a master plan for population education. **Planning and administration** of the program were assigned to a Central Office of Population Education (COPE) within the Ministry of Education. The initial goals of COPE were to address population topics at all grade levels and to coordinate population education activities with other government and private agencies. Later, to reduce costs, emphasis focused on the high school and middle school levels. These levels were emphasized because secondary school students are closer to the age when they will actually make fertility-related decisions (216, 257).

**Curriculum planning** covered 30 concepts, which were consolidated under six headings:

- human reproduction and family life,
- family size and standards of living,
- population and the environment,
- population and the economy,
- the effects of population phenomena on human life,
- population policies and programs.

Population concepts related to each heading were included in mathematics, Korean history, social studies, science, physical education, and home economics courses. In secondary school separate population units were included in the curriculum, while in primary grades concepts were incorporated into existing units.

COPE's original in-service **teacher training** plan was to provide 5-day training sessions during school vacations for 35,000 primary school teachers, 15,000 middle and high school teachers, and 2,000 school administrators by the summer of 1977. When the program emphasis shifted to the middle and high schools levels, these teacher training goals were revised. Under the revised plan 6,000 high school teachers and 11,500 middle school teachers had attended 3-day training sessions by 1978. Before the training sessions teachers and COPE staff participated in workshops to develop appropriate training materials. Primary school teachers have received only a training booklet (246).

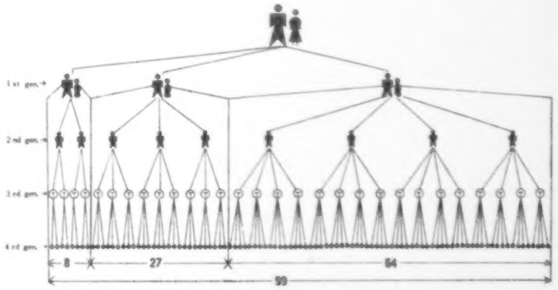
Pre-service training programs have made limited progress. Four national universities have specific optional population education courses or have integrated population topics into established courses. Some provincial colleges have been given funds to develop population education courses adapted to regional needs (104, 246).

Teachers' guides, student workbooks, audiovisual aids, and other **materials** were produced by the Korean Education Development Institute (KEDI) under the supervision of COPE (107). Materials address the 30 selected population concepts and utilize teaching techniques that encourage student participation. In 1976 KEDI published two model population education learning units, "Population Size in Korea and Betterment of the Living Standard" for a fifth-grade social studies course and "Population Urbanization: Causes, Results, and Solution Measures" for a seventh-grade social studies course (106). Both of these units stressed the negative effects of population growth and the behavior and policies that would contribute to slowing population growth.

Three field tests of secondary and upper primary level population education materials between 1974 and 1976 led to the following recommendations for the Korean program:

- Human reproduction should be taught in population education programs.
- Population education should focus directly on population problems and the attitudes and actions needed to solve the problems rather than on general population concepts.
- Teachers should have close guidance when first working through population education lessons.
- Population concepts should be introduced as separate units at the secondary level and incorporated into existing lessons at the primary level (106).

**Evaluation** of Korean population education has included surveys of attitudes toward population education as well as field tests and analyses of curricula, materials, teacher progress, and student achievement (34, 100, 106, 246) (see Evaluation, p. M-224). Most research has been conducted by KEDI and by COPE, with some assistance from universities. In Korea, as elsewhere, evaluations indicate that a major barrier to incorporating population education into the school system is teachers' lack of confidence in dealing with both the subject matter and the new, discussion-oriented teaching methods, especially when sensitive and potentially embarrassing topics are to be discussed.



**Charts can help teachers explain population concepts. This Korean chart shows the effect of family size on population growth: If each couple has 2 children, in the fourth generation there will be 8 people for every 2 in the first generation. If each couple has 4 children, in the fourth generation there will be 64.**

Source: Korean Educational Development Institute [KEDI]. Teacher's guide for population education in social studies of grade 1st, 2nd, and 3rd in elementary. Seoul, KEDI, November 1974. (107)

lation matters in the content of school programs in the region is the hope that this will lead to a change in behavior"—that is, to smaller families (250).

Another, related goal in such countries is to build support in the schools and community for national population policies. In Indonesia, for example, one of the objectives is

> to develop a positive attitude towards population policies and programmes of the country and a preparedness for active support of population programs as part of an overall development effort. (295)

National population programs may include promoting later marriage, slowing the rate of rural-to-urban migration, and increasing the participation of women in development, as well as encouraging family planning and promoting a variety of other development objectives (161, 283).

In contrast to Asia, many sub-Saharan African and Latin American countries do not have explicit population policies. In Africa, if population education programs are undertaken, the goals tend to be improving health, preserving family values, and increasing awareness of environmental stress (33, 52, 344). An exception is Upper Volta, where population education is part of a sex education program (218). In many Latin American and Caribbean countries, an implicit goal of in-school programs has been to reduce high rates of adolescent pregnancy, abortion, and sexually transmitted diseases (219, 368). In the late 1960s Colombia and Chile both initiated programs stressing population awareness, but implementation has been very limited (see Table 2, p. M-232). Even where there are no national population policies, population education can serve a useful purpose by introducing the younger generation to basic demographic information.

In developed countries most governments do not have national population policies or programs. In-school activities range from mandatory sex education in Sweden (82) to locally prepared courses, such as the Baltimore, Maryland, program in the US, that stress community, national, or global demographic and environmental concerns (69) (see p. M-214).

### Prescriptive or Nonprescriptive Approach?

Regardless of officially stated goals, a basic issue in implementing population education is: Should teachers and prepared materials actively promote specific attitudes and behavior (prescriptive approach), or should they only present facts and offer different points of view on population issues (nonprescriptive approach)? Advocates of a prescriptive approach point out that one of the immediate goals of most population education programs is to make students aware that smaller families are desirable. Thus, they argue, this point should be specifically emphasized in school (61, 221). An example of the prescriptive approach is a skit performed in a Chinese kindergarten (168) (see box, this page).

Proponents of a nonprescriptive approach argue that population education should be, if not value-free, at least value-fair (333). In other words, even if the goal is to reduce fertility, different views should be presented so that students can learn to reason and to analyze population issues and reach their own conclusions. Proponents of this view, who include many Western educators, suggest that population should be viewed "not as a problem to be solved but as a phenomenon to be understood" (338). In nonprescriptive programs the major goal is to promote "population literacy"—an understanding of basic demography, the effects of population changes, the interaction of population issues and government policies, and the effects of individual behavior on population trends (125, 338).

## "FAMILY PLANNING IS GOOD"

*Excerpt from a dialogue recited by children in the kindergarten, Hei-chuang-hu Production Brigade, Shuang-ch'iao Commune, Ch'ao-yang District, Peking Municipality, People's Republic of China, shows the highly prescriptive nature of in-school population activities in China.*

**Together:** Family planning is good; let us commit Chairman Mao's teachings to memory. For the nation, and for the world, dear uncles and aunts, let us not forget it.

**Hsiao-an:** My name is Hsiao-an; I have an older sister who is all of thirteen; older sister loves me, and I love older sister; the two of us are a pair of good companions. Father labors in the rice fields; mother is busy in the vegetable patch. To criticize Lin and criticize Confucius we rush to the fore; we learn of theory and engage in criticism; we are wholeheartedly for collectivization; and wish to contribute more to the revolution. After we have supper, father narrates family history to me and mother teaches me to sing songs. Older sister is my counselor; the study of Chairman Mao's works comes first. Together we compile children's songs; we shall never forget the class struggle; we are little people, but our ambitions are great . . . .

**Hsiao-kang:** My name is Hsiao-kang. I have a host of older brothers and sisters, and also have a younger sister named Hsiao-fang. I am not a good talker, and merely make random remarks. Father and mother are busy at their work; our family affairs are in a complete jumble; older brothers and sisters are of no avail. They bother mother until she is truly frustrated. I, Hsiao-kang, am like a little sheep; I run around as I please and bump into everything. My little friends tattle on me; so when I get home, I shall surely get slapped. You who are called Hsiao-an, let me ask you: Why is your family able to study and to criticize, while my family from day to night is always in one big mess, and is always in a meaningless uproar?

**Hsiao-an:** You who are called Hsiao-kang, listen to what I have to say: You must not forget Chairman Mao's teaching; family planning is most important; and your father and mother have not carried it out.

**Hsiao-kang:** You who are called Hsiao-an, what you have said is true; you have correctly found the root; I, Hsiao-kang, for myself, I understand, and I shall learn to propagandize family planning.

**Hsiao-an:** Hsiao-kang, let us both go among our uncles and aunts to propagandize on this topic!

Source: Orleans (168)

Regardless of theoretical advantages or disadvantages, population education programs tend to be prescriptive if the government has a clear population policy that is actively implemented. They tend to be nonprescriptive if there is fear of religious, cultural, or political opposition to family planning. In Sri Lanka, for instance, where the policy is nonprescriptive, one population educator pointed out:

> It was not our business to advocate the small family norm. We would not do anything to create direct conflict with socio-cultural and socio-religious norms that may be cherished by certain sections of the society. (20)

In a comparison of three Asian programs, R. Antony Gnanarajah and Stewart Fraser point out that population education activities in Sri Lanka, Singapore, and Indonesia "reflect essentially political rather than educational realities of the situation" (72). The nonprescriptive approach that prevails in Sri Lanka is theoretically designed to help in "making decisions through informed, reasoned process." Yet the curriculum does not spell out "the steps through which such concepts or skills would be introduced and taught to the students" (72). The researchers attribute this lack of specific guidance in Sri Lanka to religious and ethnic opposition and to shifting political and bureaucratic leadership within the government.

In Singapore, on the other hand, the population education program promotes a simple and direct "small family, good citizen" message. For example, primary school teachers in Singapore are encouraged to "ridicule out of existence pictures and charts glorifying large families" (72). Although clearly prescriptive, school activities are part of a comprehensive national program that appears to have public support. The Indonesian population education program, following a political tradition of rule by consensus, has taken a middle course. Rational persuasion is stressed as a means to convince students of the value of small families.

### Basic Content

The content of population education programs is influenced by the specific national situation as well as by political and educational goals. Most programs include several topics: (1) the current population situation, (2) basic demographic concepts, (3) the consequences of population change, and sometimes (4) human reproduction and family planning (194). The amount of time and emphasis given to each subject varies widely. (See p. M-222 for a listing of the topics included in the Philippine primary school population education program.)

In Asia the content of population education focuses on "population trends and the quality of life." For instance, a population education sourcebook prepared by an Indian educator during an overseas study tour includes sections on:

- trends of population change in India,
- the population of India in world perspective,
- projections of population change (theory),
- factors of population change (theory),
- the relationship between population and resources (theory),
- population and agricultural production,
- population and nutrition,
- population and resources,
- population and environmental pollution (413).

By contrast, in most sub-Saharan African countries, health issues, urbanization, migration, and environmental issues are emphasized more than the effects of high fertility (31, 33, 52). In many Latin American and Caribbean countries, education about human sexuality and family life takes priority over demographic issues (368). In these areas the term "family life education" is more widely used than "population education" to describe these efforts.

The content of population education may need to be adapted to a specific setting—for example, to a country, to urban or rural communities, or to a geographic region. In South Korea, where national unity is a major concern, population topics are closely integrated with Korean history and at the same time stress smaller families (246). In some countries regional adaptation may be needed. The Philippine program, which at first used the same materials nationwide, has since made efforts to localize population education content (118).

### Sex Education or Not?

A major issue is whether population education should include human reproduction and family planning methods. Logically, programs that have as a goal teaching individuals to think and behave rationally should provide full information about alternative ways to behave. Also, in countries where out-of-school publicity about family planning is widespread, the lack of in-school sex education may create a curious contrast (121). In fact, however, fear of adverse public reaction often deters edu-

**Table 4. Literacy and School Enrollment Rates in Selected Areas with Population Education Activities**

| Region & Country | Adult Literacy Rate[a] | Years of Required School Attendance[b] | % of School-Age Children in School[c] | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Primary Level | | | Secondary Level | | |
| | | | Total | Male | Female | Total | Male | Female |
| **ASIA** | | | | | | | | |
| **Bangladesh** | 26 | 0 | 72 | 103 | 40 | 22 | 32 | 11 |
| **China, People's Rep. of** | 66 | NA | 112 | 111 | 114 | 72 | 86 | 59 |
| **India** | 36 | 5 | 79 | 94 | 63 | 28 | 37 | 18 |
| **Indonesia** | 62 | 6 | 80 | 84 | 76 | 22 | 27 | 18 |
| **Korea, Rep. of** | 93 | 6 | 111 | 112 | 111 | 74 | 81 | 67 |
| **Malaysia** | 60 | 0/6[d] | 94 | 95 | 92 | 48 | 52 | 44 |
| **Nepal** | 19 | 5 | 69 | 104 | 31 | 14 | 22 | 5 |
| **Pakistan** | 24 | 0 | 50 | 68 | 31 | 17 | 25 | 8 |
| **Philippines** | 88 | 6 | 105 | 102 | 107 | 56 | 65 | 47 |
| **Singapore** | 77[e] | 0 | 109 | 111 | 107 | 57 | 56 | 58 |
| **Sri Lanka** | 85 | 10 | 94 | 98 | 90 | 52 | 63 | 40 |
| **Thailand** | 84 | 7 | 82 | 85 | 78 | 28 | 29 | 27 |
| **AFRICA & MIDDLE EAST** | | | | | | | | |
| **Egypt** | 44 | 6 | 74 | 88 | 58 | 47 | 60 | 35 |
| **Kenya** | 45 | 0 | 99 | 105 | 94 | 18 | 22 | 14 |
| **Mauritius** | 61[e] | 7 | 104 | 105 | 103 | 51 | 53 | 49 |
| **Nigeria** | 25[e] | 6 | 32 | 41 | 24 | 6 | 8 | 4 |
| **Sierra Leone** | 10[e] | 0 | 37 | 45 | 30 | 12 | 16 | 8 |
| **Tunisia** | 62 | 6 | 100 | 117 | 83 | 24 | 30 | 18 |
| **LATIN AMERICA** | | | | | | | | |
| **Chile** | 99[e] | 8 | 118 | 118 | 117 | 52 | 49 | 55 |
| **Colombia** | 72[e] | 5 | 124 | 122 | 127 | 43 | 43 | 44 |
| **Dominican Republic** | 67 | 7 | 94 | 94 | 95 | 26 | 27 | 26 |
| **El Salvador** | 62 | 9 | 79 | 80 | 77 | 23 | 25 | 21 |
| **Nicaragua** | 90 | 6 | 85 | 83 | 88 | 26 | 25 | 28 |
| **Paraguay** | 84 | 6 | 102 | 106 | 98 | 25 | 26 | 25 |
| **NORTH AMERICA** | | | | | | | | |
| **Baltimore, USA** | 99 | 10[f] | 108[g] | NA | NA | 82[g] | NA | NA |

NA = not available

[a] Source: World Bank (358) except where otherwise noted. Data for 1974–1976, for population over age 15.

[b] Source: UNESCO (244). Almost all compulsory school attendance regulations exempt a child if there is no suitable school within reasonable distance of home. Data for 1980.

[c] Source: UNESCO (244) except where otherwise noted. Data mostly for 1977–1979. Percentages greater than 100 appear because the numerator of the enrollment ratio includes pupils of all ages, while the denominator is limited to the range of typical school ages. Therefore, the gross enrollment ratio may exceed 100 percent if the actual age distribution of pupils is broader than the official school ages. School age varies by country, and in many cases children attending primary school are older than the officially prescribed ages.

[d] No compulsory education in penisular Malaysia; 6 years compulsory education in Sabah and Sarawak.

[e] Source: US Department of State (326)

[f] Source: Baltimore City Public Schools (371)

[g] Source: Maryland State Department of Education (122, 124). Figures include approximations of private and religious school enrollment.

cators from dealing fully with human reproduction in the schools. In India, South Korea, Kenya, and the Philippines, for example, surveys have shown that teachers and parents generally favor including population issues in school curricula, but they are concerned about what children will be taught about sex and family planning (81, 100, 226, 328). For this reason programs in Bangladesh, Indonesia, Malaysia, Pakistan, and Sri Lanka avoid the subjects of sex and family planning, even though many administrators acknowledge the importance of teaching students that babies are not simply a "gift from God" (132). Fear of adverse community reaction may be exaggerated, however. In Mexico, for instance, Gustavo Cavrera Acevedo, Director of the National Population Council, reports that research on sex education through television shows public opposition to be a myth (374).

Recognizing national differences, UNFPA teams reviewing overall population programs urged that South Korea now consider adding sex education to the extensive in-school program (313) but recommended that Kenya clearly separate education for family welfare from "contraceptive education" (299). In Bangladesh teachers are given some training in sex education, but the subject is not taught in the schools (290).

As part of the planning process, community attitudes and values often are assessed through surveys, seminars, and consultations. In Tunisia community leaders were consulted both to learn their reactions as well as to promote population education (246). In Indonesia various religious bodies have been regularly consulted (118). In the Philippines a survey showed that most Muslims preferred big families because "big families will bring a sure number of followers in instances where trouble may arise or a family member may go into politics" (17). Consequently, population education units developed for Muslim students do not emphasize the advantages of small families or the effects of population growth. Instead, they emphasize concern for the family, relationships between parents and children, and the need to preserve land for future generations (17). Similar attitudes may be found among minority groups in other countries and can influence the content and emphasis of population education.

### Primary or Secondary School Students?

The decision whether to include population education in primary schools, secondary schools, or both is an important one. On one hand, there are many arguments favoring the primary schools. In most developing countries enrollment in primary schools is two to four times greater than in secondary schools. In nearly all the countries listed in Table 4, fewer than half the boys and even fewer girls go on to secondary school. Even if enrollment figures are not precise, they show that most children do not reach secondary school. In fact, most rural villages do not have secondary schools, and older children may attend the primary school (36). Because of high drop-out rates, many educators recommend a strong population education program at the primary level, with special attention to girls (19, 36, 109, 110).

Moreover, the children who do not continue schooling beyond primary level are most likely to have larger families (44)—an important consideration if reducing fertility is a program goal. These children are also most likely to remain in the villages, where their education may give them increased influence (36). Even a little population education may help them eventually to plan for themselves and their communities.

Evaluations in South Korea and the Philippines suggest that, where population education units are taught in both primary and secondary schools, the younger children show a greater gain in knowledge (62, 106) (see p. M-229). This is partly because younger children, not having been exposed to other sources of information, know less about population issues before taking these units. In addition, the material studied in primary schools is brief and simple. It can focus on a few key issues, such as the concept of planning a family rather than leaving family size to chance.

On the other hand, some educators argue that population concepts should be introduced only at the secondary school level since (1) secondary school students can better understand complex population education material, (2) they are closer to childbearing age, and (3) they will ultimately be decision-makers in their countries (423). Also, because of the smaller number of students, teachers, and schools, it is less expensive and much easier to organize new programs at the secondary school level.

Ideally, of course, population education should be included in appropriate subjects in both primary and secondary schools. But experience in South Korea, the Philippines, India, and Thailand, where plans originally called for population education at all levels, suggests that training teachers and developing materials for all grades at once may be too difficult and costly (86, 154, 234, 246, 257). In Indonesia the program began with three upper primary/middle school grades and then expanded (348). This phased strategy may be more efficient than trying to introduce population education in all grades at once (86, 348).

## ADMINISTRATION

Population education programs are usually administered by a unit within the ministry of education, as in the Philippines and South Korea. In Malaysia, Sri Lanka, and Thailand a population education cell was established within the curriculum development center of the ministry. In both Singapore and Indonesia, where political support for prescriptive programs is strong, the population education programs are linked with government family planning programs. The Singapore program is jointly administered by the Family Planning and Population Board and the Ministry of Education. The Indonesian program is under the general supervision of the National Family Planning Coordinating Board (BKKBN) but is administered by the Ministry of Education and Culture (76, 86). In Mexico population education is part of the sex education project of the National Population Council (60, 287).

Many different groups are involved in a population education program besides the teachers and students. Thus extensive orientation and coordination are necessary from the start. Once the political decision is made to develop a national program—and sometimes even before—ministry officials, administrators, supervisors, and academic experts need to be informed and convinced. Support from the top is essential to carry out any extensive changes in education. Regional workshops and overseas study tours paved the way for the first programs. Subsequently, national seminars have been held in Chile, Colombia, India, Indonesia, Malaysia, Nepal, the Philippines, Sri Lanka, Thailand, Sierra Leone, and Kenya (472). After a program begins, in-country training is often particularly useful since it can focus on problems specific to the area (243).

### Coordination and Testing

Coordination is necessary throughout the educational system. This includes regional educational units in provinces and

# Population Education in the US: Baltimore

In the United States in-school education is a responsibility of state and local rather than national government. Community involvement in education is the rule, and it is important that parents and local leaders approve of the curriculum. In the case of education about human reproduction and family planning, community acceptance is particularly important because these subjects are often controversial.

National activities in population education have been limited. In 1972 the President's Commission on Population and the American Future recommended that population courses be included in the schools (7). Teacher training workshops and classroom materials have been developed by private agencies such as Planned Parenthood/World Population, the Population Reference Bureau, and Zero Population Growth. Several of these programs were funded under the 1970 Environmental Education Act. A Population Education Act, proposed in 1970, did not pass, however (146).

Courses specifically on population education are not generally available in US schools, mainly because of lack of central support but also because of lack of materials and training opportunities (84). Only a few teachers colleges, including Columbia University (New York), the University of North Carolina Florida State University, and Towson State University (Maryland), offer training in population education (4, 609). Materials often are available only through private agencies. Nevertheless, many individual teachers raise the subject and include population topics in courses on the environment or contemporary issues (16, 146, 150, 195).

### The Baltimore Program

Only one population education program exists that covers an entire school district—in the city of Baltimore, Maryland, with a school population of about 122,000 students. The program was started by Caroline Cochran, a Planned Parenthood/World Population volunteer, and Lester McCrea, a social studies teacher. They took the initiative in winning approval from the school system, raising $250,000 from private foundations for curriculum development, and holding teacher training workshops. The focus of the program is on demographic concepts, social issues, and urban life. Human reproduction (supposedly covered elsewhere in the curriculum) and family planning were not included because of concern over community opposition. The program no longer requires outside funding. It is now an established part of the curriculum.

In-service **teacher training** began in 1972-73 with nine 3-day urban life-population education workshops, each of which was evaluated by outside observers. In each workshop 30 teachers were introduced to population and urban issues, including controversial issues such as the emerging new role of women and the perception of some US minorities that family planning is equivalent to racial genocide. The workshops tested three different approaches to training. Evaluations showed that teachers learned the most from a formal presentation of basic facts followed by small-group discussions (42, 67). Evaluation also showed that primary school teachers found it harder to master the material than secondary school teachers (67). More workshops have been held since, but they are shorter in order to reduce costs.

During the summer of 1973 nine teachers, selected from workshop participants, developed classroom **materials** for four different units. The materials were produced inexpensively. They contained few errors and were well-suited to local needs (239). After testing, four units were revised and reproduced for use in all Baltimore City schools beginning in 1975. Since 1975 they have been periodically revised and updated using reactions from teachers (42). The units are:

- *Life Around Me* (primary school), an introduction to demography (505),
- *B-More Baltimore!* (secondary school), a survey of the city's historical growth and places of interest (503),
- *Interplay: The American Family* (secondary school), a review of the role of students as future family decision-makers (504),
- *Production, Pollution, Population: Issues for a Changing World* (secondary school), a presentation of global population issues (506).

The primary level unit contains a number of activities, worksheets, and home assignments. Each secondary level unit contains 10 lessons that can last from one to three days, depending on the amount of supplemental material included. They cover such topics as differences among family units around the world, pressures on families, and attitudes affecting family size. All units are complete, ready to use, and include practical suggestions on how to present the material, such as lists of objectives, detailed outlines, complete home assignments, class assignments, and summary questions.

The Baltimore program has undergone more extensive **evaluation** than most programs. Experts from The Johns Hopkins University evaluated the workshops (67). Teachers as well as outside experts evaluated the materials (239). In addition, student achievement, attitudes, and behavior after completing a unit were evaluated (181). It was found that ninth grade students who had studied the *B-More Baltimore!* unit knew significantly more about Baltimore and about population-related urban problems in their city than a control group. In addition, students who had studied the unit had a more negative attitude toward population growth than the controls. No changes were observed in utilization of city services and agencies (181) (see p. M-231).

It took about five years and several dedicated people to start the Baltimore program. The success of the program can be attributed to several factors. Strong promotion by volunteers and effective guidance within the Baltimore school system helped win official support. Persistent follow-through ensured that the program was actually carried out. Finally, the materials used in the classroom were produced by teachers themselves and were "clear, concrete and well worked out to require little additional teacher time in preparation of lessons. . ." (240). They were easily understood by teachers and students. So far this combination of factors has not been duplicated anywhere else in the US.

cities, which in some countries have considerable autonomy; subject specialists in such different fields as biology, social science, and home economics; curriculum developers and textbook publishers; universities and teacher training centers; and principals and teachers in thousands of schools. Some of these come under the direct jurisdiction of the education ministry, but others may be quite independent. In Indonesia and the Philippines, for example, two-thirds to three-quarters of secondary schools are not operated by the government (72, 268). Thus in many cases the population education unit has a massive task to perform but limited authority to enforce its recommendations.

Coordination with other groups is also important. Parents and community leaders should be fully informed and encouraged to support the program. Experience has shown that programs which have strong local roots and are felt to meet local needs are most likely to be implemented (19, 23). Family planning agencies also can contribute to national in-school activities—for example, by training teachers or providing materials. Population education programs may benefit from close coordination with these agencies (86). Nevertheless, some educators are reluctant to be closely linked with family planning activities.

Another important area where coordination is valuable is in standardized grade and subject testing. A cost-effective way to ensure that key population concepts are taught is to include questions about them in any standardized national or regional test. A World Bank review of examination reform noted that, for the two school years before students take any standardized examination, the "effective curriculum of the class is defined ...by the content of the most recent selection examination paper" (370). Thus, changing the content of exam questions is likely to cause more rapid curriculum change than in-service training or changes in official syllabi. As one educator has pointed out,

> our experience in Hong Kong suggests that in selective and highly competitive systems like ours, it is the public examination which provides the pivot around which the innovator might best turn the curriculum. (121)

Partly as a result of the AHEA-sponsored program in Jamaica (see p. M-209), questions on family planning were included in the Caribbean standardized examinations on home economics (13). In West Africa efforts are being made to include population issues in regional tests (314) (see p. M-226). In the Philippines an international team reviewing the population education program urged that population questions be included on both college entrance and civil service examinations (311).

### Funding

Adequate long-term funding is necessary to carry out a population education program. Some of the original impetus for population education came from outside sources, such as family planning associations, then USAID, UNFPA, UNESCO, and the World Bank (see Table 3, p. M-235). In general, UNFPA supports government population education activities carried out by ministries of education (312). So far UNFPA has allocated about $20 million (US) for this work. UNESCO provides technical assistance, frequently from regional offices in Asia, Africa, and Latin America and using traveling teams of experts (275). In addition to construction loans for school facilities and equipment, the World Bank has supported national population education programs as one part of more comprehensive education loans that cover the costs of curriculum development, preparation of materials, and teacher training (134). USAID assistance, at a much lower level, usually supports activities of private agencies, including, for example, a project to incorporate family planning into the teaching of home economics, various workshops, publications, and pilot projects (186). A problem for many funding agencies is that project cycles usually run for three to five years, whereas population education programs may not show results for almost a decade.

Outside funding has the advantage of permitting innovation when budgets are tight, but it also has disadvantages. For example, local input may be limited, or the funding may be abruptly ended. In the Dominican Republic, for instance, UNFPA funding for population education will end in 1982 even though a 1980 review praised the program's progress (288, 364). The proportion of internal funds contributed to population education programs generally is substantial. It is difficult to quantify, however, since ministries often provide facilities, equipment, and support staff rather than specific amounts of money.

Although needs for additional funding from outside sources should be minimal once a population education program is fully established and institutionalized, the process of innovation takes time. Five years is the minimum time necessary to introduce a new subject in a school system (129), and usually it takes longer. Without a long-term commitment by national leaders to provide indigenous funds, population education programs may be planned and administered on paper but not fully implemented in the classrooms.

## CURRICULUM PLANNING

Once basic program content has been determined, incorporating population education into a school curriculum involves further decisions, such as:

- Will population issues be taught in separate courses or will they be integrated in some way into existing courses?
- What population concepts are best suited for particular subjects and/or grade levels?

In some countries—for example, Indonesia, Sri Lanka, Nepal, and Sierra Leone—efforts to include population education in the curriculum have coincided with renovation of the entire curriculum. In other countries—for example, the Philippines, India, and Tunisia—population topics had to be carefully worked into already established courses. Where population education can be introduced at the same time that basic textbooks and teachers' guides are revised, the process is organizationally simpler and less costly. Such revisions may occur only once or twice each decade, however.

Sometimes existing courses can readily be expanded to include population education. In El Salvador, for instance, secondary-level biology courses already included "human reproduction," "nutrition, food and population," and "man and his environment," so additional material on population could be readily included (246). By contrast, in South Korea a study done before the population education program began found that only one-third of one percent of the content in all school books related to population topics (34).

### Separate or Integrated Courses?

Population content can be introduced either through an entirely separate course or as additional topics incorporated into existing courses (the "infusion" approach). Separate courses

**Rapid population growth contributes to many problems of education—crowded classrooms, overburdened teachers, shortages of materials, and insufficient teacher training.** (UNESCO)

mean less revision of existing curricula and fewer teachers to be retrained. The teachers offering separate courses, however, need extensive training, and many national curricula do not have room for a new course. Infusing population data and concepts into existing courses means less in-depth training but more teachers to train and more revision of existing courses (130, 207). Especially at the secondary level, most programs compromise by using a unit integration approach, in which several population topics are inserted as a unit into established courses. For the most part, separate courses are used only at the college level, while infusing material into existing courses is used at the primary school level.

Where units or other materials are integrated or infused into existing courses, experience in Sri Lanka and Indonesia suggests that they add 5 to 7 percent to the total time required for a course (133). This can be a continuing problem. A Philippine survey of teachers and administrators found that lack of time was one of the most serious problems in implementing population education (62).

The Korean Educational Development Institute (KEDI) has completed a number of studies of "curricular organization" for population education to determine which approach teachers prefer (106). After two trials, in 1974 and 1975, teachers reported that the unit integration approach was more effective than the infusion approach. A more detailed follow-up study, lasting over two months and involving 48 schools and 10 subjects, was completed in 1976. The teachers involved concluded that the more flexible infusion approach was most effective in primary grades, while the unit approach was most effective in secondary grades (106). Primary school teachers preferred the infusion approach in part because they considered self-contained units such as "Population and Employment" to be too difficult for their students.

### Identifying Subjects and Grades

The next step in integrating population topics with an established curriculum is to determine what concepts should be introduced in what courses at what levels. Numerous outlines and hierarchically organized lists of population education objectives and concepts are available to help during the early stages of this process (99, 110, 156, 222, 266). It is often difficult, however, to maintain the logical order of a content outline when matching content to various courses and grade levels. Usually, a "scope and sequence chart"—a matrix of major concepts, grade levels, and subjects—is developed during the process (53) (see p. M-222).

Much attention has been given to finding the best "plug point" (a term coined by Indian educators) to insert population materials into established curricula (99, 110, 155, 224). For example, "Population Education Curriculum for Schools," published by the state of Tamil Nadu in south India, lists the appropriate plug point, content, and activities for each concept to be included in the program (414). In primary schools a mathematics lesson on direct proportions becomes a plug point for the concept "when the number in a family increases, the population increases." A suggested activity is visiting a district government office to collect data on family and population size for use in class. In Indonesia a secondary-school geography unit on census results becomes a plug point for the topics of mortality and migration (75).

Deciding where to introduce population material in secondary school subjects is complicated by the fact that, in higher grades, students often take standardized tests on traditional subjects such as biology, history, and mother language. Thus secondary school teachers and students are reluctant to "dilute" these key subjects with population material, particularly since most standardized tests have not yet been updated to include questions about population (121). For these reasons population education is often introduced in lower secondary grades (grades 7–9), where performance on standardized tests is not stressed, or else it is introduced in nontested subjects.

At the primary level the curriculum is usually more flexible (207). Nevertheless, it may not be possible to introduce population topics in a logical order in primary grades because some topics are too difficult for younger children. For instance, of 1,083 Thai primary school teachers surveyed in 1972, only 16 percent felt that "methods of solving population problems" or "family planning" should be taught in primary schools. Only 21 percent thought that primary school students should be taught about "the consequences of population change." Nonetheless, 51 percent felt that their students should be taught the more straightforward topic "population characteristics of Thailand and nearby countries" (228). Some programs do appear to be too difficult at the primary school level. In South Korea, for example, 10-year-olds have been expected to answer multiple choice questions such as, "What is the most desirable way to reduce the difference between population density in rural and urban areas?" and 12-year-olds were asked, "What is an accurate description of the relationship between population increase and national health?" (106). The difficulty of population content was confirmed in an evaluation of the learning skills required to answer questions on a population literacy test developed by the UNESCO Regional Office for Education in Asia and Oceania (258). Of the 30 questions, 20 required relatively sophisticated learning skills (258).

### Micro and Macro Approaches

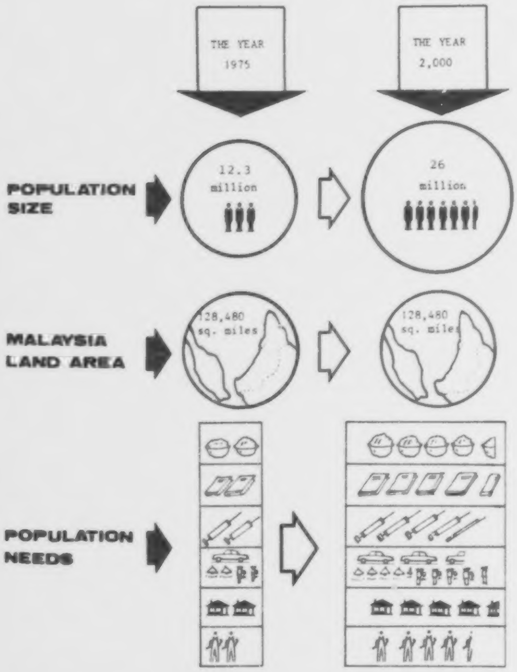
One way to deal with complex content in primary grades is to use a "micro"—personal or family—approach rather than a "macro"—national or global—approach. In population education seminars sponsored by the Danish Family Planning Association in 1972 and 1975, curriculum developers from Egypt, Indonesia, Bangladesh, Nepal, and elsewhere prepared materials for 9- to 11-year-olds that emphasized individuals and the family (50, 51). In 1975 the Pakistani delegation prepared a curricular plan and teaching materials using a particular family to illustrate the effects of rural-urban migration. The plan and materials emphasized pollution, unemployment, expense, and overcrowding in urban areas (51). By contrast, a Philippine second-year high school mathematics course takes a macro approach to the rural-urban migration issue. The unit covers urban dependency ratios, population densities in rural and urban areas, and migration rates in and out of rural areas (544).

In contrast to both micro and macro concepts, the Malaysian program uses a hierarchical approach. The ideas introduced are basic at the primary level but become progressively more complex at the middle and upper secondary school levels. For instance, under the topic "population, resources, and the environment," content at the primary level is "types of resources and environments." Content at the lower secondary level includes "effects of rapid population growth on the environment," and at the upper secondary level, "interdependence of countries in relation to resources" (117).

## TEACHER TRAINING

Ultimately, only the classroom teachers can really implement a population education program. Thus the most important task—and one of the most difficult—is teacher training. While teachers themselves are rarely in a position to plan and promote national programs, without their support the plans developed by experts and officials will never be fully implemented. Experience in population education suggests that the more teachers participate in the processes of curriculum development and training, the more likely they are to carry out the program (17, 75, 239). To be effective in the long run, training in population education must reach high proportions of current classroom teachers (in-service training) and of those studying to become teachers (pre-service training).

***CONSEQUENCES OF THE DEMOGRAPHIC SITUATION***



**Self-Learning Educational Modules, or SLEMs, have been used to speed the training of in-service teachers. A diagram from a SLEM for Malaysian teachers shows the impact of national population growth.**
Source: Malaysia. Curriculum Development Center. Population self-learning package for teachers. Malaysia, Ministry of Education, [1980]. (455)

### In-Service Training Strategies

In-service teacher training is the biggest challenge in any population education program. First, the number of teachers who must be trained is massive, especially if primary school is included. In Indonesia, for example, the school system consists of over 100,000 primary and secondary schools in which population education is required (75). In Egypt plans call for training more than 200,000 teachers (133, 292). Second, many of the teachers, especially in the primary schools, have limited education themselves. In India, for example, primary level teachers have as little as one year of schooling after secondary school (128). Third, most teachers are not knowledgeable about population data and concepts. For instance, in India, population education reportedly has been "popularized" since 1969. Yet a 1976 study of secondary school teachers in Bombay found that 54 percent had never heard of population education (328).

Various strategies have been suggested for training large numbers of teachers:

- face-to-face training by experts or supervisors in short courses or workshops,
- peer training, in which trained teachers instruct other teachers in their schools,
- Self-Learning Educational Modules (SLEMs), which introduce teachers to population education through self-explanatory booklets,
- correspondence courses using standard population education training material.

**Face-to-face training** has been widely used. Most programs involve several stages with, for example, national or international experts training district-level supervisors, who train school principals, who in turn train classroom teachers. The shortcomings are obvious: the quality of the training tends to decline at each new level (19). Classroom teachers may receive a very inadequate introduction to the subject (145). Training sessions for the classroom teachers are usually short—in the Philippines, for example, less than one week, compared with five weeks for the supervisors (19). In such short sessions it is impossible to address all aspects of population education (62, 232). In addition, providing face-to-face training for all teachers requires training facilities and personnel, payment of travel expenses, and considerable time either during the school year or during holidays.

A variation is **peer training**. In Indonesia and Sri Lanka teacher-trainers in each school are being trained in population education so that they can train other teachers in the school (72). In Thailand peer training is underway. Some 2,500 teachers trained at regional institutes are expected to train other teachers in their schools (56). This approach requires strong motivation on the part of teacher-trainers and is limited by many of the same difficulties that limit other face-to-face training strategies.

Because of these problems, Malaysia developed self-learning booklets in the mid-1970s in order to reach all teachers directly with an "unadulterated" population education message (116). Called **Self-Learning Educational Modules** (SLEMs), the booklets usually include a list of learning objectives, descriptions of major issues, questions (with answers supplied), a glossary, and a reference list.

# Population Education in Egypt

As part of the national population program in Egypt, in 1970 the Ministry of Education began efforts to introduce population issues into the school curriculum. The first step was a survey of existing texts to determine how well they covered population-related topics. Between 1974 and 1976 population topics were integrated into a number of existing subjects. In 1977 a small Office of Population and Environmental Education (OPEE) was established (292).

To date OPEE has concentrated on developing background material and curriculum guides and particularly on orienting supervisory personnel (292). For instance, 23 different booklets have been prepared describing the major concepts and methods of population education. Also, 15,000 copies of an Arabic edition of Lane and Wileman's *A Structure for Population Education* were distributed to Egyptian educators (109). The book includes a detailed content outline, list of objectives, and reference list (110). Implementation in the schools has been limited.

Training of key personnel has involved three approaches: (1) overseas study tours, (2) correspondence courses, and (3) national workshops funded by the US Agency for International Development. OPEE staff members were sent on overseas study tours. District supervisors and interested teachers take the year-long correspondence courses. The courses present a detailed overview of the economic and environmental effects of population growth. Each 10-day workshop (held yearly since 1977) involves as many as 60 district supervisors, teacher trainers, and teachers who have completed the correspondence courses. The workshops have been jointly led by the Egyptian population education staff and population education consultants. They have used a variety of approaches. The 1979 workshop, headed by Byron Massialas, involved lectures by Egyptian officials and a series of small-group activities that introduced participants to teaching strategies (126). The 1980 workshop, headed by Mary Turner Lane, focused on the content of population education, clarifying relationships with development and environmental issues. In addition, participants were helped to develop complete lesson plans for classroom use (111). The 1981 workshop, described below, emphasized new teaching techniques.

# Introducing New Teaching Methods: A Workshop

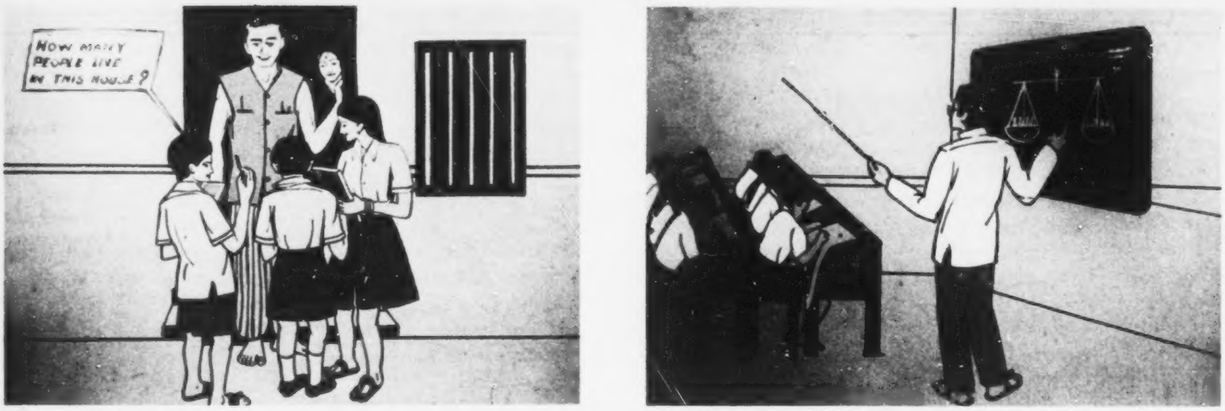
*Elaine Murphy, Ph.D., Director of Population Education, Population Reference Bureau, Washington, D.C.*

The 1981 training workshop in Alexandria, Egypt, was jointly led by Mohammed Gamil, Supervisor of the OPEE, and by Elaine Murphy and Patricia Cancellier of the Population Reference Bureau (PRB). The main function of the workshop was to help participants adapt methods and materials developed in the US and elsewhere to suit Egyptian schools. The 45 participants, all former teachers, were district supervisors of various disciplines. They were expected, after taking the course, to organize similar workshops at the district level for classroom teachers.

Workshop participants were introduced to a variety of teaching methods using the "inquiry approach." The inquiry, or discovery, approach departs from the tradition of having students memorize facts and figures. Instead, students inquire into the causes of a situation and draw conclusions from their own investigations and analyses. During the 1981 workshop, participants practiced inquiry-based approaches for primary or secondary school classes:

- **Small-group work**. The participants were given data on the growth of Egypt's population since 1800. Their assignment was: "Using inexpensive, locally available materials (such as seeds, beans, and poster board), work in small groups to develop a way to illustrate how Egypt's population density increased between 1800 and 1980." One group drew four rough maps of Egypt on poster board and labeled them 1830, 1880, 1930, and 1980. The group then placed progressively larger numbers of dry beans within the borders of each map to show increases in population density. The activity, including each group's demonstration and practical critiques by the whole group, took about two hours.
- **Simulations**. A simulation illustrated the dynamics of population growth. A fish bowl represented the earth, a cup of water poured into it represented annual births, half a cup of water taken out represented annual deaths, and a large water bucket, from which "births" were drawn and to which "deaths" returned, represented "the great beyond." Participants were asked to draw conclusions from the simulation. The educators noted that high birthrates and low death rates result in obvious population growth—a rising water level. Thus the speed of growth was dramatically illustrated.
- **Making tables and charts**. An important aspect of population literacy is using graphs and tables. One activity involved selecting four slowly growing countries and four rapidly growing countries from PRB's *World Population Data Sheet* (an annually published chart that lists 14 demographic variables for most nations). To compare the two types of countries, participants developed a table that illustrated differences in key variables—for example, life expectancy, infant mortality, and gross national product (GNP) per person. They were then asked to make generalizations from their tables. Finally, participants discussed not only the generalizations but also the usefulness of such student-centered work in Egyptian schools.

Other workshop activities included: the use of pictures or articles to stimulate discussion of population issues; collection and classification of old sayings and traditions that encourage or discourage large families; "values clarification," in which a series of statements about family size—for instance, "I think that the government should reward people for having small families"—were distributed and participants expressed and discussed their opinions; and role playing, in which participants acted as members of a local population planning council trying to develop strategies to reduce the birthrate in their community.


HOW MANY PEOPLE LIVE IN THIS HOUSE?

**A UNESCO slide and tape show introduces teachers to population education and basic demography. The show points out that taking a community census is a practical way for students to learn simple demographic concepts (left). A diagram can help the teacher point out that the quality of life is best when population size and available resources balance (right). UNESCO Regional Offices can provide materials like these.**

While inexpensive, SLEMs provide little personal interaction for the teachers. Whether this is good or bad may depend on custom. In a pilot test involving 50 Malaysian schools, the self-learning approach was modified somewhat. Headmasters were trained as "module managers" to supervise and monitor teachers' progress with SLEMs. Each headmaster conducted nine 2- to 3-hour sessions for 15 teachers in which they led discussions, answered questions, and evaluated oral reports. Two difficulties arose: (1) Most headmasters were not confident of their own knowledge of population education. (2) The interaction expected between headmaster and teacher was unfamiliar, since the headmaster had to depart from his usual authoritarian role. This made both teachers and headmasters uneasy (94). The opposite problem occurred in the Philippines, where teachers, used to personal interaction and guidance in learning, found independent work difficult. Still, the Philippines Population Education Program concluded, in a study of 540 primary school teachers, that SLEMs provided an "effective alternative . . . to face-to-face training" (246).

**Correspondence courses** have been used less often than face-to-face training and SLEMs. Little has been reported about their effectiveness. In Pakistan an 18-unit correspondence course has reportedly been used to train half of the nation's 100,000 primary school teachers (56).

The reports available indicate that all four strategies can be used to prepare teachers to present population issues in the classroom (232, 611). Because each has different advantages and disadvantages, programs tend to use a method, or sometimes a variety of methods, that suits the financial and administrative capabilities of the program.

### In-Service Training Problems

Whatever the training method, evaluations of teacher training show that teachers often do not learn enough to feel confident of their ability to prepare population education lessons. In a 1980 survey of 270 Philippine primary school teachers who had received up to five days of training, 62 percent felt that the training in population education had improved their teaching ability. Fifty-four percent felt that their lack of knowledge was still a serious or extremely serious problem, however (62).

The brief training received by most teachers often does not prepare them to use innovative teaching methods such as the inquiry approach and values clarification (see p. M-204). Teachers in the Philippines found that the discussion and question-and-answer methods suggested in curriculum guides were difficult to use. Observers noted that teachers tended to "rely heavily on the printed page" and, in many cases, to be "unable to handle student discussions" (17). Moreover, brief training may not be enough to prepare teachers to answer questions not covered in the official curriculum. For instance, although the Malaysian program does not include sex and family planning topics, pilot tests showed that some units, such as "Population Change, Its Determinants and Consequences," stimulated questions and comments from students about sex and family planning for which teachers were unprepared (94).

Initial training should be bolstered by continuing help and encouragement. In the Philippine survey of teachers over 45 percent wanted more help learning population content, applying new teaching methods, using materials, and evaluating students (62). Such help could include a regular newsletter, complete sample lessons, and advice from supervisors or department heads. In South Korea radio broadcasts for teachers supplement population education training (205).

Overall, many teachers in developing countries are burdened by large classes, poor facilities, and a lack of materials (8). Classroom teachers need extensive training, support, and strong personal motivation to undertake additional tasks.

### Pre-Service Training

Pre-service training may be even more important to the long-term effectiveness of a population education program than in-service training. There is a shortage of well-trained teachers in most developing countries (8, 357). Yet the number of school-age children will increase for at least the next decade. Thus teacher training institutions will have to produce more graduates to meet growing needs. If all current and future teacher trainees learn about population issues as a routine part of initial training, population education could be institutionalized in school systems at a minimal cost.

Despite the importance of pre-service training, in most countries it has not received as much emphasis as in-service training. There are at least two reasons for this: First, pre-service training is rarely under the direct supervision of population education central administrators. Instead, it is in the hands of universities, colleges, or teacher training institutes. Second, in some institutions of higher education, population education is not viewed as a legitimate academic or scholarly enterprise. Thus it may be difficult to find qualified and enthusiastic instructors and to obtain administrative support (472).

There are marked variations in the extent of pre-service training. In the Philippines, cooperating training institutions offer a 3-credit course, for which the population education central office has prepared an extensive outline (470). At one university teacher trainees can major in population education. At other institutions, however, a population education course is not required and in a few, none is offered.

Comparing pre-service training in Singapore, Sri Lanka, and Indonesia, Gnanarajah and Fraser found many inconsistencies (72). In Indonesia a decree from the Ministry of Education and Culture in 1976 made population education mandatory in teacher training institutions (134). Some now offer a well-received population education course in which various lecturers discuss their specialties. In other Indonesian training institutions, however, population education is discussed only as a minor part of a social science program. Sri Lankan teacher trainees are supposed to work through a 15-hour series of population education modules at some point during their training. In fact, some students are exposed to only a few hours of lectures. In Singapore, where population education is supposedly a stable component of primary school curricula, there is no organized population education course offered to teacher trainees (72). This may reflect the strong orientation toward family planning goals rather than educational goals.

The problems of introducing population education into teacher training colleges mirror the problems of introducing population education in schools—inadequately prepared instructors, lack of materials, and limited evaluation of achievement. In Bangladesh population education was introduced in secondary teacher training colleges in 1976–77. A 1979–80 study found that teacher trainees at five colleges learned little about population education during the academic year (a 1- to 3-point gain out of a 25-point total). Although 94 percent thought that they knew enough to teach population issues, 75 percent thought that insufficient time had been devoted to the topic, and 63 percent felt that the population education syllabi were not clear. The nine college instructors involved in the study generally lectured, and only four reported requiring any practical work. The instructors complained that materials were lacking and that no questions about population were included in the final examinations prepared by college officials (362).

**Sixth graders in the Philippines use workbooks to learn about the effects of population growth. Student workbooks are valuable classroom aids, but most programs cannot afford to supply them regularly to every student.** (Philippines Population Education Program)

In 1980 UNESCO published a survey and analysis of teacher training activities as a guide for preparation of the forthcoming *Handbook for Teacher Training in Population Education, Family Life Education and Sex Education*. Major recommendations were:

(1) include population, family life, and sex education in the curriculum of training institutions,
(2) provide teacher trainees with experiences that will build the skills and attitudes needed to teach these topics,
(3) prepare teachers to take part in other areas of a new program besides classroom teaching, such as evaluation and management,
(4) involve teacher training colleges in all aspects of a new program, such as curriculum development and in-service training (472).

All of these recommendations involve increasing the role of teachers colleges in the implementation of a new program. Unless teacher training institutions incorporate the subject into their own curricula, the stability of a population education program will remain in doubt.

## TEACHING MATERIALS

A major barrier to population education programs is the lack of suitable teaching materials (243). Most programs develop teachers' guides, which list the topics and objectives of each unit and occasionally suggest activities and test questions. Many programs also prepare sourcebooks, which provide background information on population education and population topics. Materials of these types are not much help with classroom activities, however, particularly for teachers who know little about population issues and do not have time to prepare complete lessons.

To be useful in classrooms, teaching materials should suggest specific, feasible activities that teachers can organize quickly and simply. The Family Planning Association of Hong Kong, for instance, published a *Teacher's Handbook for Population Education*. After each chapter the handbook suggests class discussion topics and student activities. For example,

1. Draw graphs of the following, or illustrate them in other, more vivid ways:
    a) Population growth in Hong Kong since 1935, indicating related historical events if possible.
    b) Changes in population growth by area distribution, 1911–1971.
    c) Trends of birth and death rates since the Second World War.
    d) Projection of population growth in Hong Kong from 1971 to 1991. (401)

Even more detailed materials are used in the Baltimore population education program (see box, p. M-214). Each lesson plan includes learning objectives, detailed descriptions of activities, complete home assignments, and tests. The lessons were developed by teachers and were designed to require as little time and work as possible from the teachers using them. In Baltimore,

## Locating Population Education Materials

The material available in population education can be grouped into five categories:

**Sourcebooks**, also known as handbooks or resource books, may summarize population topics, government policies, and the rationale for population education. Some of these are collections of materials useful for population education although not specifically prepared for this use. Others may discuss particular aspects of the design or implementation of a population education program—teacher training, curriculum planning, or integration of population education into a specific subject. Both types may be designed for a particular audience, but they are generally helpful to planners, curriculum developers, and teachers. Selected sourcebooks are listed on p. M-242 (400–424).

**Teacher training materials** are generally designed to be used by teachers to train themselves and/or by professional teacher trainers. They range from short units on population education to training manuals for week-long sessions. Selected teacher training materials are listed on p. M-242 (450–473).

**Teaching materials** are those used in the classroom. They include complete lesson outlines, wall charts, and student texts and workbooks. Selected teaching materials are listed on p. M-242 (500–561).

**Lists of references and teaching aids** catalogue the materials listed above. Selected lists are found on p. M-243 (600–624).

**Newsletters and periodicals** in population education report on regional or national developments (for example, the UNESCO/Bangkok *Newsletter*), discuss a particular topic in depth (for example, the UNESCO/Santiago bulletin *Enlace*), list recent publications, or serve several of these functions.

Many of these materials are produced for use in a particular country or region, but often they are adaptable, especially in the case of teaching materials. Some materials are available free of charge. There are also a number of publications available for those interested in establishing population education reference centers (184, 188, 210, 259–262).

Listed below are the major organizations that prepare or provide these materials and the type of material available from each. In addition, national population education programs generally supply materials that they have developed to interested professionals.

**American Home Economics Association**
**International Family Planning Project**
**2010 Massachusetts Avenue, N.W.**
**Washington, D.C. 20036**
**USA**
*Sourcebooks, teaching materials, reference lists, newsletter.*

**International Planned Parenthood Federation**
**18–20 Lower Regent Street**
**London, SW1Y 4PW**
**UK**
*Sourcebooks, teaching materials, reference lists.*

**Population Reference Bureau**
**P.O. Box 35012**
**Washington, D.C. 20013**
**USA**
*Sourcebooks, teaching materials, reference lists, newsletter.*

**UNESCO Regional Office for Education**
**Population Education Programme Service**
**G.P.O. 1425**
**Bangkok, Thailand**
*Sourcebooks, teacher training materials, teaching materials, reference lists, newsletter.*

**UNESCO Regional Office for Education**
**Servicio Regional de Información sobre Educación en Población**
**Casilla 3187**
**Santiago, Chile**
*Sourcebook in preparation, periodic bulletin.*

**Zero Population Growth Inc.**
**1346 Connecticut Avenue, N.W.**
**Washington, D.C. 20036**
**USA**
*Sourcebooks, teaching materials, reference lists.*

where not all teachers have been trained in population education, these teaching materials help make the program work (240).

Teaching any subject, including population, is easier if straightforward, practical, and familiar teaching aids are available. When 133 teachers in Florida (US) were asked what would be most useful to them when they taught population topics, 70 percent wanted simple audiovisual aids, and 68 percent wanted student workbooks (227). Providing teachers with simple visual or audiovisual materials has been stressed by a number of experts. A progress report on the early stages of the Somalian population education program observed that "what schools need and need badly is good visual material in the form of charts, diagrams and pictures, especially in the introduction of new content" (92). The 1981 evaluation of American Home Economics Association projects in Latin America, Asia, and Africa also recommended better distribution and more use of audiovisual materials (26).

### Developing and Distributing Materials

Experience has shown that classroom teachers should be consulted and involved in the preparation of classroom materials (17, 106, 239). This involvement can help to assure that materials will be useful in the classroom and appropriate for particular groups of students. Programs that have hired professional writing teams to develop material—as in India, South Korea, and the Philippines—often have been forced to change the material substantially after it has been tried in the classroom (19, 106, 158). For instance, in the Philippines lessons dealing with human sexuality used standard tems for sexual organs and functions. Teachers attending research utilization conferences explained that, although they were willing to teach human sex-

# *Philippine Scope and Sequence Chart*

***The Philippine population education program is one of the most extensive, covering all grade levels and several subjects within each grade. A scope and sequence chart, shown here for the primary school grades only, indicates the population education subject matter in each grade and class.***

| | Social Studies | Health Education | Elementary Science | Mathematics |
|---|---|---|---|---|
| Grade I | I. The Family<br>A. What the family is<br>B. The purpose of the family<br>C. Family size and composition<br>D. Some effects of family size on some needs of the family | I. Effects of Family Size on Basic Needs<br>A. Relation of family size to food, housing and clothing needs<br>B. Effects on family health | I. The Genitals<br>A. Knowing the genital organs that differentiate boys from girls<br>B. Care of the genitals<br>1. Personal cleanliness | I. Family<br>II. Family Size<br>III. Replacement |
| Grade II | I. Population and Population Change in the Schools<br>A. What is population?<br>B. Some characteristics of a population<br>1. age<br>2. sex<br>3. occupation<br>4. size<br>5. change<br>C. The school population changes in size over time | I. Family Size and Food Needs<br>A. Family size and quantity of food requirements<br>B. Family size and quality of food requirements | I. Male and Female Characteristics<br>A. Maleness and femaleness of animals<br>1. Recognizing differences between males and females<br>2. Names of some male and female animals<br>B. Maleness and femaleness of man<br>1. Every child a boy or a girl<br>2. Characteristics that distinguish girls from boys | I. Family<br>II. Family Size<br>III. Birth<br>IV. Dependence |
| Grade III | I. Population Changes in the Community<br>A. Change of size through births<br>B. Change of size through deaths<br>C. Change of size through migration | I. Family Size and the Emotional and Social Health of Family Members<br>A. Role of the family in the emotional and social health of its members<br>B. Family size and its effects on emotional and social health | I. Overcrowding (Density) Affects Individual Needs<br>A. Needs and care of living things<br>1. Effects of overcrowding on plants, animals, and man in terms of individual share of available needs (food, space) and growth | I. Family<br>II. Family Size<br>III. Dependence<br>IV. Birth<br>V. Death<br>VI. Migration |
| Grade IV | I. Effect of Migration on Population Growth<br>A. Type of migration<br>1. Barrio to town, city to city<br>2. Town to city<br>B. Reasons for migrating<br>1. Seek jobs<br>2. Better opportunities<br>C. Effects of migration<br>1. On the place left<br>2. On the place migrated to<br>D. Characteristics of migrants | I. Population Size, School Health Personnel and Facilities, and Community Health Service<br>A. Effects of school population on the quality of school health services and facilities<br>B. Effects of population size on the quality of health services in the community | I. Non-Human Population<br>A. Relationship between some animal's capacity to reproduce and some environmental factors<br>B. Balance of nature (Introduction to ecology) | I. Birth<br>II. Death<br>III. Migration<br>IV. Population Status<br>V. Population Growth<br>VI. Age Groups<br>VII. Projections |

| | Social Studies | Health Education | Elementary Science | Home Economics | Mathematics |
|---|---|---|---|---|---|
| Grade V | I. Family Size<br>A. Family size norm in the Philippines<br>1. Completed family size<br>B. Factors that promote large family size<br>1. Custom, practices, beliefs<br>2. Government measures<br>C. Relationship between family size and population growth | I. Changes in Mortality<br>A. Changes in mortality over time<br>B. Factors that contribute to mortality decline | I. Man's Adaptation to the Environment<br>A. Rate of population growth (RPG) and the use of agricultural lands and forest areas for housing<br>1. Agricultural lands used as subdivision<br>2. Forest areas used for housing<br>B. RPG and maximum utilization of resources<br>1. Improved agriculture | I. Some of the Changes in Boys and Girls at Puberty<br>A. Growth in height and weight<br>B. Development of breasts<br>C. Widening of hips<br>D. Growth of pubic hair<br>E. Menstruation in girls<br>F. Ejaculation in boys<br>II. Significance of some pubertal changes to fertility behavior | I. Population status<br>II. Projection<br>III. Birth Rate<br>IV. Death Rate<br>V. Rate of Natural Increase<br>VI. Life Expectancy<br>VII. Population Density<br>VIII. Dependency Ratio |
| Grade VI | I. Consequences of RPG on Family and Community<br>A. Economic<br>B. Health<br>C. Food Production<br>D. Education<br>E. Environment<br>F. Socio-psychological<br>II. Planning and Decision Making<br>A. Importance of planning and decision making<br>B. Making a decision on family size | I. Some Consequences of RPG on Community Health<br>A. Some consequences of RPG which directly affect man's health and well-being<br>B. Government's effort to solve problems brought about by RPG | I. Some Effects of RPG on Man's Environment<br>A. Man's rapid population growth may upset the balance of nature<br>1. Destruction of natural habitats of other living things<br>2. Overexploitation and/or depletion of resources<br>3. Pollution<br>B. Need for Conservation<br>1. Government policies<br>2. Reforestation | I. Age at Marriage<br>A. Advantages/disadvantages of early/late marriage<br>B. Customs, beliefs, and practices that influence age at marriage<br>C. Laws regulating age at marriage<br>D. Relation of age at marriage to number of children and standard of living | I. Birth Rate<br>II. Death Rate<br>III. Migration Rate<br>IV. Rate of Natural Increase<br>V. Growth Rate<br>VI. Dependency Ratio<br>VII. Life Expectancy<br>VIII. Population Density<br>IX. Population Projections |

**Source: adopted from UNESCO. Co-ordinated Action Programme for the Advancement of Population Education. Study of the contribution of population education to educational renewal and innovation in El Salvador. Republic of Korea, Philippines and Tunisia. Paris, UNESCO, 1980. (246)**

# A Lesson for Philippine Fifth Graders

*This Philippines social studies lesson is one of five that make up the fifth grade population education unit "Determinants of Family Size." The unit encourages students to examine and question beliefs and customs about family size. A list of influences on family size accompanies the lesson plan.*

**A. Objectives**

1. Explain how the government policies and social practices encourage a large or a small family size.
   a. State some laws or decrees that influence family size.
   b. Cite some practices in society that favor a large family size.
2. Examine critically existing beliefs and practices in the light of individual, as well as societal needs.
3. Determine a desirable family size.

**B. Content**

1. How Government Policies and Social Practices Encourage a Large Family Size

**C. Suggested Procedure**

**Opener**

Have the pupils read the following news items from the *Bulletin Today* (July 30, 1973; March 19, 1973).

*News Item No. 1*

In August, 1973, Singapore started enforcing a new set of laws that would make couples have fewer children. They are the following:

(1) A couple would have to pay higher hospital bills for every child born.
(2) Tax deductions or exemptions are for the first three children only.
(3) An employed mother in Singapore can enjoy paid maternity leaves for the first two children only.
(4) Couples with two or fewer children will be given the first chance to occupy apartments and housing units.

*News Item No. 2*

A Spanish couple with 18 children has won a prize of 150,000 pesetas (nearly 3,000 dollars) for being the largest family in Spain. Mr. and Mrs. Rojas said after being given money by the Spanish government, "It follows (because of the prize) that we will have some more children."

**Development**

Watch the pupils' reactions on both news items. Have them give their comments. Then discuss the items along the following lines:

> Compare the new items. Which government favors a small family size? A large family size? What about our government? What does it favor?

Draw out the fact that the trend in our country used to be favorable to a large family size by having the pupils answer the following questions:

> How long could a permanent teacher go on maternity leave with pay? How much would she get?

Have the pupil who was assigned to get the desired information report his findings.

> Is the maternity leave with pay favorable to having more children? Why? Compare the situation here with that in Singapore. If a female employee or teacher does not get paid when she has her baby, do you think this would affect her family size? How? (Perhaps she would space her babies to reduce the number of children she will have.)
>
> What government policies encourage a large family size?

Draw out the fact that it used to be that all children below 18 years meant a ₱1,000 [$138 (US)] deduction each for the parents when they paid their income taxes.

> Is this still true today?

If the pupils don't know the answer, explain that in Presidential Decree No. 69 entitled *Amending Certain Sections of the National Revenue Code*, the number of dependents who can be considered for exemptions have been reduced to *four* only for those families who will have additional children born after December, 1973.

> Besides the government, our society also favors a large family size.

Discuss the Parents-of-the-Year Award given to U.P. [University of the Philippines] graduates whose many children also finished their courses at the State University; also the giving of prizes to couples with the most number of children during class reunions; the deductions in matriculation fees of sisters and brothers attending the same school or university; etc.

**Summing Up**

> Based on our lesson and discussions today, would you say that some government policies influence family size? What about our own government and our own society?

Lead the children to give the following statements. Write the statements on the chalkboard:

1. Some governments encourage a large family size. Some governments have laws that favor small families.
2. Our government used to promote a large family size. Now it has started to promote a small family size.
3. Some practices in our society promote a large family size.

Source: Philippines Department of Education and Culture. Population Education Program [PEP]. Teacher's guide in population education for social studies, grades 1-6. Manila, PEP, 1975. (538)

uality, they found it difficult and embarassing to explain to students what these standard terms meant. It would be better, they said, to use vernacular terms (341). The relatively new Sierra Leone program is involving teachers in the process of developing materials. Writing teams made up of secondary school teachers develop materials and then revise them after pilot tests (see box, p. M-226).

Population education materials are now available from a number of sources. Population textbooks (347, 353) and pamphlets on population issues (29, 167) can provide general information. Several organizations, including the Population Reference Bureau (PRB), the International Planned Parenthood Federation (IPPF), and the UNESCO Regional Office for Asia and Oceania, prepare and publish complete population education lessons, student materials, and visual aids that can be used as is or adapted to specific needs (see box, p. M-221). In addition, many individual teachers around the world have developed materials that work well in their classrooms. Simple visual aids can be easily prepared. An AHEA *Media Resource Book* offers a guide to making materials such as posters and flip charts (14). More sharing of specific lesson plans and classroom materials would help to develop a pool of proven teaching materials (143).

After appropriate materials have been developed, there are obvious practical steps to take before they reach teachers and students. First, in many countries materials must be translated into regional languages. In India very few materials were available in Hindi or Tamil (the predominant regional languages) during the 1970s (154), and in the Philippines most materials were originally printed in English rather than in the national language, Pilipino (17). Second, materials must be printed quickly. In Sierra Leone difficulties with the government printing office delayed publication of a population education supplement for the eighth grade social studies course (79). Third, materials must be distributed to *all* involved teachers. In Indonesia 382 rural and urban secondary school teachers who were supposed to be teaching population education were surveyed in 1979. The survey revealed that only 22 percent had been provided with textbooks on population education and only 21 percent had been provided with teachers' guides. Observers in Asian countries have reported that sometimes new materials reach only the district administrators or at best the school administrators and not the teachers.

**The range of population education materials is wide and comes from sources as diverse as UNESCO offices, the Tamil Nadu State Council of Educational Research and Training in India, and the American Home Economics Association. Many of these workbooks, newsletters, sourcebooks, and lists of classroom activities are available to interested individuals who request copies (see p. M-221).**

Where education systems provide textbooks, the best way to ensure that all schools receive and use population materials is to see that the basic texts include population content. Virtually all teachers—whether prepared and motivated or not—will teach what is in the basic textbooks. Periodic textbook revisions provide a good opportunity for changes. In Mexico, for instance, population and human reproduction have been incorporated into government-produced texts during the revisions that take place about every five years (11, 49). The revised books are distributed to all school children. In addition, supplemental materials about topics such as family life (48) and the effects of television on children's perceptions of sexuality and sex roles (47) are available to teachers and administrators.

Lack of funds is one reason that teachers and students do not have appropriate classroom materials on population. Providing material to all teachers or workbooks for every student in a national program is expensive. In some countries teachers who want their own guides or tests must buy them with their own money (129, 219, 230). Without useful, reusable materials, whether locally made or distributed by a central unit, population education cannot be fully implemented in schools.

## EVALUATION

Like all education, population education programs are difficult to evaluate. As yet there is no accepted system for evaluation (133). Most of the evaluations to date fall into one of four categories:

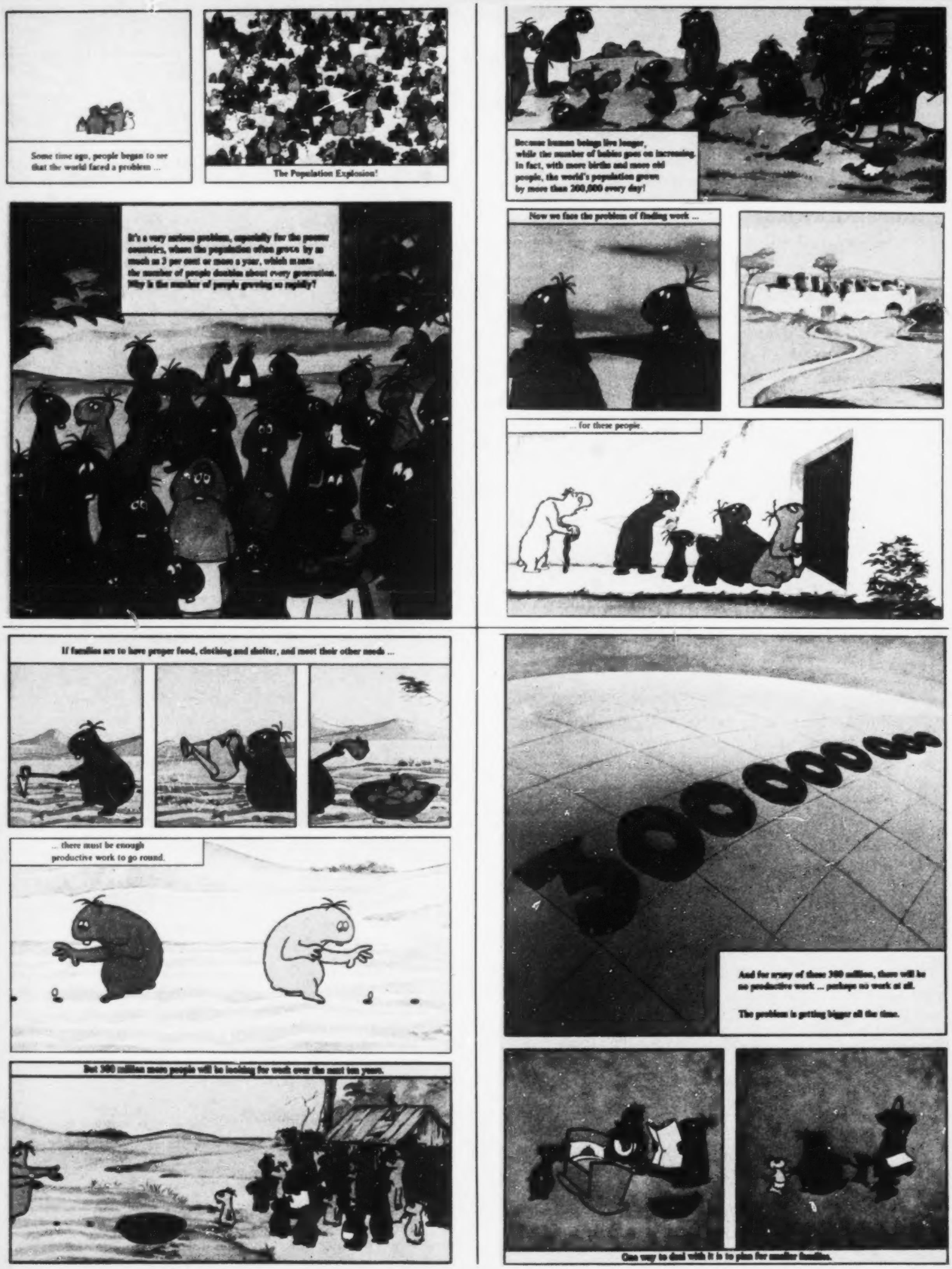
- baseline studies focusing on teacher, student, and community attitudes and curriculum content before the program begins,
- operational research, focusing on pilot tests of curriculum changes, new units, materials, and teacher training strategies (sometimes called "formative evaluation"),
- assessments of implementation, focusing on the extent of teacher training, materials development, and, to a lesser degree, on classroom application,
- measurement of impact on students in terms of changes in knowledge, attitudes, and—in the future perhaps—fertility-related behavior (96, 103).

Baseline studies are usually designed to find out what goals and content would be acceptable to the teachers and the community. Surveys have been undertaken, for example, in India (182, 183, 328), Kenya (81), the Philippines (62), Thailand (229), the US (84), and Ghana (71) (see p. M-213). Qualitative assessments based on case studies have been carried out by UNESCO in Morocco, Peru, Rwanda, and Tanzania (245).

Operational research has been used to pretest curriculum guides, teaching materials, and new training strategies. Most national programs conduct extensive pretesting before any new teaching material is introduced into the curriculum (17, 79, 106, 246). Different teacher training strategies have been compared in Baltimore (67), Malaysia (116), and the Philippines (145) (see p. M-217). Operational research is used in the development of specific materials or activities, and much of it is not published or readily available.

### Assessing Program Implementation

Evaluations of program progress have been carried out by funding and technical assistance agencies in many countries. These


Some time ago, people began to see that the world faced a problem ...
The Population Explosion!
It's a very serious problem, especially for the poorer countries, where the population often grows by as much as 3 per cent or more a year, which means the number of people doubles about every generation. Why is the number of people growing so rapidly?
Because human beings live longer, while the number of babies goes on increasing. In fact, with more births and more old people, the world's population grows by more than 200,000 every day!
Now we face the problem of finding work ...
... for these people.
If families are to have proper food, clothing and shelter, and meet their other needs ...
... there must be enough productive work to go round.
But 300 million more people will be looking for work over the next ten years.
300000000
And for many of these 300 million, there will be no productive work ... perhaps no work at all.
The problem is getting bigger all the time.
One way to deal with it is to plan for smaller families.

**The brightly colored comic book *300,000,000* has been one of the most widely distributed population education materials since it was issued in 1975. The book's furry, one-toothed creatures illustrate the relationship between population growth and jobs. Smaller families will help solve the problem, as these excerpts illustrate. But, the book continues, the 300,000,000 job-seekers already born face many problems finding work. The comic book is based on a short film. Both were prepared for the International Labour Organization (ILO) with financial support from UNFPA. Limited numbers of copies are available in English, French, Spanish, or Arabic from the ILO, Ch-1211, Geneva, Switzerland.**

# Population Education in Sierra Leone

Sierra Leone has the only established national program in Africa south of the Sahara (242), although a program is beginning in Somalia (92) and some planning is underway elsewhere (see Table 2, p. M-232). The Sierra Leone program, funded by UNFPA, aims at integrating population education into the country's new secondary-level social studies curriculum (79).

Implementation of the program began in 1977 but has been limited by both political and educational factors. First, the Sierra Leone government does not officially recognize population growth as a problem, even though the population growth rate increased from 2.2 percent in the 1960s to 2.5 percent in the 1970s (161, 283, 358). Instead, reducing mortality and morbidity, improving population distribution between rural and urban areas, and limiting immigration are stressed (161, 283). Second, educational resources are limited. Government expenditure on education during the late 1970s was less than $20 (US) per school-age child (compared with more than $1,000 in many developed countries) (244). Third, well over half of school-age children are not enrolled in school. In 1977 only 37 percent of the children of primary-school age and 12 percent of the children of secondary-school age were enrolled (244). Thus the program will reach only a small percentage of the nation's children.

### Creating Awareness

The Institute of Education of the University of Sierra Leone, a government organization, is responsible for the **planning and administration** of the program, including curriculum development, staff training, and materials preparation (79, 143). The ultimate goal is to create a widespread "awareness of the implications and consequences of population growth on the socio-economic development of the country" (79). Specifically, students would

> eventually be able to make informed and rational decisions on matters relating to population, like when to marry, how many wives to marry, when to have children, size of family and to make positive moves toward ensuring improved quality of life for their family, community, and nation. (79)

Short-term goals include developing a corps of experts in population education, integrating population concepts into secondary school and teachers college curricula, and training a group of teachers who will organize peer training sessions in schools.

**Curriculum planning** was simplified considerably by the decision of the Ministry of Education to introduce population education through the new secondary-level social studies curriculum. A 1977 conference concluded that the program should be limited to the first three of five secondary forms (grades 8–10), since students in forms four and five prepare for an external examination (79). The subject matter is primarily population dynamics, population and family life, and population and ecology.

**Teacher training** is still in the early stages. Five members of the project staff were trained through overseas study tours and fellowships during 1977–79 (79). Of the approximately 2,500 secondary-level teachers in the country (244), 1,330 have been targeted for in-service training (314). As of 1979 only about 100 teachers had attended workshops that introduced them to population concepts, materials, and inquiry teaching methods (79). Some teachers were introduced to population education through the efforts of an American Home Economics Association (AHEA)–US Agency for International Development (USAID) project. The project, designed to introduce family planning, family life, and some population information through home economics activities, has sponsored training workshops for in-service teachers and worked with teacher training colleges to include population and family planning topics in the home economics curriculum (26, 143). Some of the teachers reached by the project have adapted AHEA materials for classroom use (26). Pre-service training for teachers of other subjects is still in the planning stage.

### Teachers Develop Materials

The development of **materials** was the responsibility of a writing team of four secondary-level teachers on assignment with the Institute of Education beginning in 1978. For form one, this team designed a supplement to the social studies text already produced. The text discusses man and his abilities. The supplement adds information on the structure and composition of populations and on family life. This supplement was tested in 24 schools during the 1978–79 school year, then revised and published for national distribution the following year. The basic text for form two, which discusses man and his environment, had not yet been prepared when materials development began in 1978. Therefore the writing team was able to incorporate population content into the text directly, without a supplement. The new text was introduced on a pilot basis in the 1979-80 school year. A draft of a student text and teacher's guide for form three were tested in 12 schools in 1981 (164). Distribution of these materials has been seriously hindered by delays in printing and other difficulties (164).

**Evaluation** has been limited (79, 314). Teachers' comments on the effectiveness of the materials were used to revise them after pilot testing. Students' knowledge before and after exposure to the new materials was assessed. The results have not been published.

An important development for population education in Sierra Leone is the possible inclusion of population questions, drawn from the project, in the West African Examination Council's widely used exams (314, 355). This would provide standardized assessment at minimal cost of the impact of population education on students' knowledge. In addition, it would encourage and facilitate the development of population education programs by other countries in the region.

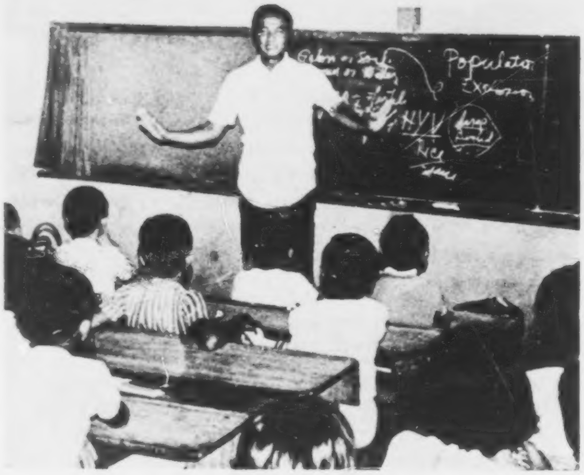
evaluations seek to determine whether plans are being implemented and funds effectively used. Tripartite reviews by UNFPA, UNESCO, and host-government education ministries were conducted in Bangladesh (189), the Dominican Republic (219), India (279), Indonesia, South Korea, Malaysia, Mexico (219), Sierra Leone (164), and Somalia (219) in 1980 and 1981. Tripartite reviews are scheduled for 1982 in Nicaragua, Paraguay, Sudan, and Tunisia (219). These reviews are usually carried out in cooperation with regional offices of UNESCO, and reports are not widely circulated. In addition, UNFPA has supported program evaluations by expert groups in Bangladesh (208) and Sri Lanka (209); evaluation seminars in Togo and Upper Volta (219); and evaluation missions to Benin (219) and El Salvador (213). These tripartite reviews and expert evaluations focus on problems in program implementation. They frequently lead to such specific recommendations as a need for more funding and cooperation with universities in Bangladesh (189) and the need for more training of key personnel and provision of UNESCO reference materials in Sierra Leone (164).

A number of general reviews, called Needs Assessments, were undertaken for UNFPA during 1978–81 to determine the overall needs of national population programs. Conducted by international teams of population experts, these reviews usually include a brief summary of population education activities to date and recommendations for further action. Needs Assessments reports that discuss population education are available on a number of countries, including Bangladesh (290), Egypt (292), India (293), Indonesia (294), Kenya (299), South Korea (in draft) (313), Malaysia (301), Nepal (305), Pakistan (373), the Philippines (311), Sri Lanka (315), Thailand (320), and Tunisia (324).

Many of these reviews have stressed the need to develop or expand a cadre of population education experts in the government or universities to work on curriculum development and textbook revision (292, 294, 299, 301, 305, 313). Study tours to see programs in other countries have been cited as an effective way to stimulate the interest of educators (292, 299, 301, 313) and to develop the necessary high-level support (301). Reviews also recommended the expansion of teacher training in Egypt (292), Nepal (304), and Pakistan (373), where programs are just beginning to be implemented, as well as in Korea (313), where three days of training in new teaching techniques was not considered sufficient (313), and in Sri Lanka, where the peer training strategy was not considered extensive enough (315). Ministries of education were urged to develop simple, locally appropriate materials and strategies for the classroom, ranging from textbooks in Indonesia (294), Kenya (313), South Korea (313), and Nepal (303) to visual aids in the Philippines (311) and Pakistan (373) and educational television in Egypt (292).

### Evaluating Classroom Application

Program directors and funding agencies continually try to find out whether programs are reaching the target population, but in the field of education this is particularly difficult. Most of the time teachers work independently, and constant supervision is impossible. Moreover, as in family planning programs, estimates of the number of people reached and progress reports made by supervisors are often overly optimistic. Measuring the extent of implementation is necessary, however. If the program has not been implemented, any study of program impact or effectiveness may be an attempt to study a nonevent (75). Thus, just as contraceptive prevalence surveys have been developed to measure the impact of family planning programs, so also population education prevalence surveys might be useful to estimate the extent of population education in the classroom.



**Students often gain knowledge when studying population issues, but changes in attitude are less common. Here a visiting agricultural worker tells Philippine third graders how population growth affects food supply.** (Philippines Population Education Program)

In the Philippines reports differ on the extent of classroom implementation. In 1979 the UNFPA Needs Assessment team noted that "teachers seem to devote very little time to population questions in the classroom, according to a PEP [Population Education Program] survey and independent evaluations" (311). One explanation was that teachers' guides were too detailed and academic and that the textbooks did not contain enough population material (311). In a 1980 survey of 270 primary school teachers and 68 administrators, however, more than 30 percent of the teachers reported that they were "involved in helping to implement" the program to a great or very great extent; 51 percent reported that they were involved "to some extent" (62). About 62 percent of the teachers reported that they integrated population into existing subject areas. Over half deviated slightly (46 percent) or significantly (about 8 percent) from the prescribed daily subject matter and teaching strategies, compared with about 45 percent who followed them very closely (62).

The main reasons that the Philippine teachers gave for accepting and implementing population education were that the project was a response to government concern about population problems (48 percent) and that there was a need for the project to help solve population problems (31 percent). The main obstacles were lack of time in the curriculum, inadequate knowledge of the subject, and lack of funds (62).

The Indonesian program, which, like the Philippine program, has been underway for almost a decade, also has had some problems with implementation (75). A survey of 382 junior and senior high school teachers in rural and urban areas of Jogyakarta province found that about 40 percent never taught population education in their classes, while about 35 percent often or regularly integrated population with other topics or gave relevant assignments (75).

The Indonesian teachers most likely to teach about population were those who had been exposed to the field through training, access to materials, and classroom supervision of their teaching. About 25 percent of the teachers had taken special preservice training, and 22 percent had taken in-service training. About 20 percent had received textbooks or teachers' guides

## Population Education in India

Although population education was first discussed in India in the late 1960s, implementation has been limited. The National Council of Educational Research and Training (NCERT) sponsored a national seminar in 1969 (137), which concluded that population topics should be taught at all grade levels. The proposed emphasis of the Indian program was described by the Minister of Education:

> Population education, at least as I see it, is primarily a motivational force for creating the right attitudes to family size and the need for family planning and should not be mixed up with sex education or knowledge of family planning methods. (193)

In practice, establishing population education courses in Indian schools has proved difficult. Each of the 22 Indian states operates an essentially autonomous educational system, often using different languages. Also, cultural diversity as well as the large size and population of the country have made curriculum development and teacher training a massive and still unfinished task. A 1980 survey found that, although a few states had incorporated population issues incidentally into their curricula, comprehensive, statewide programs had not been carried out because of lack of materials and trained teachers (154).

After the 1969 seminar **planning and administration** of population education efforts were assigned to a small population education cell within NCERT. Discussions of population education continued throughout the 1970s but without serious efforts to establish pilot programs in schools (89).

In the late 1970s the Ministry of Education and NCERT began making plans to introduce population education in all Indian schools except in the most remote states and territories. The Indian government and UNFPA agreed on a 3-year, $5,322,000 (US) program beginning in April 1980. Workshops (158) and a survey of state population education activities (154) were carried out to evaluate program needs. The objectives of the program include establishing state population education cells, developing prototype curricula, publishing a quarterly newsletter, and preparing instructors to train classroom teachers (85). Ten states began implementing the project in 1980, and nine more states began in 1981.

Sample curriculum outlines and guidelines for **curriculum planning**, published throughout the 1970s, can be adapted for state use (130, 157, 191). Most of these publications follow the UNESCO-Asian pattern of identifying major population concepts and their subconcepts and then describing how they can be integrated into established school programs. Many omit human reproduction and family planning because educators fear community reaction (343).

So far, **teacher training** in population education is available in only a few Indian universities. For instance, Sri Venkateswara University in Tirupati (which has a Population Studies Centre) has included population concepts in some courses and has offered special workshops and short courses (153). At present, the 19 states involved in the UNFPA-funded program are planning comprehensive training programs for their teachers.

**Materials** developed by NCERT, Sri Venkateswara University, and the Family Planning Association of India include sourcebooks on general population issues (408) as well as sourcebooks relating population to nutrition (412) and to the quality of life (407). A bibliography of population and population education readings (610) and some sample teaching materials also have been prepared. Most teaching materials were designed for secondary school use and often consist only of simple suggestions for classroom activities or short objective tests (15, 156). One of the few teaching aids designed for primary school classes is a collection of stories, poems, and short lessons about population and family life (534). How extensively these materials have been used during curriculum planning or in classrooms is not known.

**Evaluation** in the 1970s focused on population awareness and/or attitudes toward population education among students, teachers, and parents (183, 196, 266, 328) and on family size preferences of children (182). These studies indicated that surveyed students, teachers, and parents were aware of India's population problems and generally approved of discussions of the problems in schools. Despite this awareness, most students and teachers wanted three or more children. In addition, many teachers did not feel qualified to teach about population.

In 1981 a tripartite review and an annual country review pointed out the need for (1) more time to implement the program, (2) more funds, (3) better coordination between state population education cells and other education divisions, and (4) more effective guidelines for the cells (279).

on population education. To a lesser extent, acceptability of population education (including student interest, community approval, and administrative support) also influenced the extent of implementation. Demographic characteristics of the teachers, their experience, and job satisfaction were not related or were only slightly related to the extent of implementation (75).

The implementation of educational innovations depends upon many factors. Research in the United States suggests that strong local and community involvement is important during educational change (22). In countries such as the Philippines, however, centralized educational systems appear to be able to win cooperation and support of teachers (62). The few available studies suggest that implementation by teachers depends largely on adequate teacher training in the subject, ample classroom materials, and sufficient time in the curriculum. These three basic needs are far from being fully met in most programs.

## IMPACT ON STUDENTS

The ultimate test of population education is impact on the student. Very few evaluations have tried to assess the effects of population education on students, particularly on students' attitudes or behavior with respect to fertility. There are several reasons for this gap:

- Many programs are relatively new. They are only now moving beyond the planning stage and actually teaching population in the classroom.

- Identifying the impact of specific subject matter or lessons is difficult, since many other factors also influence students' knowledge, attitudes, and behavior (131, 180).
- Considerable time may pass between attending school and making fertility-related decisions. Thus a decade or more may be necessary to find out whether in-school education influences later attitudes and behavior.
- Evaluation and research in population education has not received "the attention and support that it deserves from policy makers, decision-makers, and key administrators in education" (96). The growing interest of the World Bank and the proposed UNESCO/UNFPA *Review and Comparative Assessment of Significant Country Population Education Experiences* (372) may focus more attention on the need for adequate research methodologies and evaluation.

Of the few relatively thorough evaluations of program impact, two took place in the Philippines, one in South Korea, and one in Baltimore, US. Some information also is available from Sri Lanka, Bangladesh, and Colombia, but generally data describing the impact of population education on students are meager.

**The Wesleyan Population Center in the Philippines (WPC)**, with support from the Pathfinder Fund, began developing population education materials in 1970. The material was tested at grade 4 though college level as part of such courses as social studies, science, health, history, economics, and sociology. A total of 48 teachers and 1,836 students in five primary schools, five secondary schools, and six colleges participated. Pilot classes were monitored throughout the 1973–74 school year by (1) observation of classroom experience, (2) questionnaires and meetings to assess teachers' reactions to the materials, and (3) achievement tests to measure students' performance before and after courses (17).

**The Philippine Women's University Population Education Center (PEC)**, funded by USAID from 1970 to 1972, developed population education units for grades 6 and 10 (fourth-year high school) to be included in health, science, physical education, and social studies classes. After seven months, classes using these units in 158 schools in Central Luzon, Greater Manila, and the Visayas were evaluated. Students took a 60-item multiple choice test. Random samples of 50 students and 50 controls who had not studied population education were compared. Changes in attitude were not measured (17).

**The Korean Educational Development Institute (KEDI)** has conducted several evaluations of curriculum and teacher training to assess both teacher and student reactions. One pilot study was conducted in 1976 in grades 4, 5, and 6 of 15 primary schools and all grades of 16 middle and 17 high schools, including large and small city schools, rural schools, and boys', girls', and coed schools. In each school one experimental and one control class was used--a total of 144 classes. The study analyzed (1) written tests to measure students' achievement, (2) teachers' opinions of the curriculum, (3) observations of the material in use in the classroom (106).

**The Urban Life Population Education Institute** in Baltimore, US, has developed four population education units. One of these, the *B-More Baltimore!* unit, has been a regular part of the ninth grade social studies curriculum since 1975. In the fall of 1978 questionnaires and tests were administered in seven schools to 908 students who had taken the course and to 205 students of the same age who had not. Evaluated were students' demographic and other knowledge about the city of Baltimore, attitudes toward the city and suburbs, and behavior in utilizing city facilities and services. In addition, 62 students were interviewed to learn their reactions to the unit (181).

These and other studies suggest three major conclusions about the effects of population education on students:

- Student knowledge of population issues increases as a result of studying a population unit.
- Some of the basic demographic concepts and methods of studying population issues are difficult for students to understand.
- Changes in attitudes seem to occur less often than changes in knowledge.

### Knowledge Changes

All four studies found significant increases in knowledge about population issues when students in the program were compared either with control groups (PEC, South Korea, Baltimore) or the same students before taking the courses (WPC).

In three studies younger students—those in primary school—seemed to learn more than those in higher grades. In the Wesleyan Center study primary school children scored higher in both knowledge gain and attitude change than the high school students (17). Similarly, in the PEC study the younger students did better (17). In the Korean study, primary school students studying population education consistently outperformed the control group. Substantial gains in knowledge among the younger students may reflect the fact that primary school is the first time these children become aware of population issues (106). By middle school or later, the topics may have been discussed in other courses or situations, and so initial knowledge is greater.

Students appear to find some population education units difficult. In South Korea the population education units include many complex points. Students had particular difficulty with the concepts of growth rates and migration ratios. The Korean evaluators suggested that, to make the subject easier to understand, difficult concepts should be illustrated with local examples (106). In another study Philippine high school students who had studied population and sex education for 2 ½ months in an experimental curriculum were found to dislike a number of topics, either because they were embarrassing or because they were difficult to understand (17). Certain basic terms—for instance, "rate"—proved especially difficult.

**Philippine primary school teachers work in small groups during an in-service training session. Training is most useful when it involves practical activities.** (Philippine Population Education Program)

# RECOMMENDATIONS FOR IMPROVING POPULATION EDUCATION

Based on the overall experience to date, the following specific proposals are suggested to carry out and improve national population education programs:

### Planning and Administration

- Establish a population education unit at a high level in the Ministry of Education, with authority to plan, develop, and implement the program and to cooperate with other public and private agencies (133). A curriculum development unit alone may not be enough.
- Orient high-level personnel to population issues and to the nature and goals of population education. This will help to build support for and facilitate implementation of programs throughout the school system (109).
- Issue clear directives to managers and supervisors at provincial and lower levels and follow up as required, using workshops and other means to explain the new program and to insure implementation at the local level.
- Develop programs for primary schools, where enrollment rates are highest (109).
- Start new programs on a small scale, with only a few grades and/or classes involved, then phase in new material gradually (348).
- Allow ample time early in the development of a program for pilot tests in the classroom of curriculum changes, teaching materials, and methods.
- Work with testing agencies to incorporate questions about population issues into regional or national achievement exams (121, 311, 370).
- Assess out-of-school educational activities to assure that in-school programs support and expand rather than duplicate these activities (243, 338).
- Work closely with nongovernmental agencies, religious groups, community leaders, and others to build support for the program (89, 350).

### Curriculum Planning

- Whenever possible, time the introduction of population education to coincide with overall curriculum revision so that population topics can be introduced directly into the standard textbooks and teachers' guides as they are revised (350).
- Involve classroom teachers in deciding how and when population issues should be introduced in various subjects (239).
- Focus on a few basic issues at the primary school level, such as how families grow and the need for planning in daily life, and leave more complex ideas for higher grade levels (50, 51).
- Organize special events or activities to promote population education. Such activities could include exhibitions, special "population days," essay contests, or "population oratorical competitions" for secondary school students (133, 361).

### Training Teachers

- Provide at least one week of training and preferably more, with much personal contact between trainers and teachers (62).
- Give teachers practical training, such as developing lesson plans or making simple visual aids (472).
- Provide continual opportunities for follow-up of training courses and for refresher training (205).
- Develop required courses in teacher training institutions early in program development so that in-service training needs can be reduced (472).
- Use radio broadcasts aimed specifically at teachers in order to supplement more traditional approaches (205).
- Encourage teachers at all levels to be trained in population education so that the field is not limited to experts but is recognized as a subject that everyone should know about.

### Materials

- Provide detailed classroom materials for teachers to use, such as lesson plans, descriptions of teaching methods, and textbooks (240).
- Integrate population content into basic textbooks and teachers' guides, since these are more likely to be widely distributed and used in the classroom than any supplementary material.
- Provide teaching aids, especially student booklets, workbooks, and visual materials, that can help teachers to explain difficult concepts (26).
- Keep materials as simple as possible, in the local language, and using examples relevant to the community (154). The basic objective should not be to train demographers, but to give all children some familiarity with population issues that they will face.
- Develop additional channels for sharing population education materials among countries, regions, and individuals (143).
- Where radio or television is used in the classroom for other subjects, use it for population education as well (368).

### Evaluation

- Conduct research studies to evaluate new teaching techniques or materials before they are introduced widely in the schools. Then revise curriculum plans or materials as indicated (258).
- Survey teachers to find out how much population content is actually taught in classrooms. If the level of implementation is inadequate, find out what is needed to implement the program fully (75).
- Assess the effects of various population units on student achievement to determine what types of units communicate important concepts most effectively (10).
- Experiment with methods of measuring attitudes and attitude changes—for example, asking students to imagine themselves in a specific population-related situation that would require them to choose a course of action (27).
- Recognize that the success of a program depends on strong government commitment to population policy and on stable leadership at a high level.

In Bangladesh a study of 557 fourth and fifth graders in 19 schools found little change in knowledge between January and December 1979. Scores in tests on both the population topics and the subject in which they were incorporated increased by only one to three points (363). From the report of the study, it is not clear how much time was spent on these subjects or how they were presented, however.

### Attitude Changes

Two of the studies tried to evaluate changes in students' attitudes. The Wesleyan Center study found that Philippine students changed their attitudes about family size. The number of students who preferred small families (0–4 children) "increased remarkably" after taking the course. The change was greatest among primary school students (17).

The Baltimore study reported a number of changes in students' attitudes. As expected, and most importantly, those who had taken the *B-more Baltimore!* unit had more negative attitudes toward population growth than the control group students. The other attitude changes concerned feelings about Baltimore. One-third reported more positive feelings about the city after completing the unit, while two-thirds reported no change. Surprisingly, however, compared with the controls, more of the students who had taken the course thought that the city was small and less exciting. They were more likely to consider the suburban areas of the city more pleasant than their own neighborhoods (181). Perhaps because the unit taught them about problems in Baltimore, it made them more critical. Almost half said that "improvements in the city would have made the experience of studying it a better one" (197).

A 1968 study of a pilot program in Colombia found that, along with knowledge gains, family size preference decreased from an average of about 3.1 to about 2.75 (30, 32). The impact of this attitude change on behavior is questionable, however. As the investigator, David Burleson, points out:

> Changes of this magnitude, I believe, document the development of greater population awareness. There is no guarantee that the change will become the subjects' family model. It is totally naive to expect that a short course of population dynamics in high school can have a permanent effect. However, if this impact were to be reinforced in other courses throughout the secondary school experience, a major restraint on rapid population growth might result. (30)

A 1981 UNFPA-supported evaluation of the Sri Lankan program, while it did not measure changes in knowledge or attitude, did show that students may be concerned about population problems even though their demographic knowledge is slight (209). Of the 142 tenth grade students questioned, only 11 percent correctly answered as many as 5 of 11 questions, primarily on the population of Sri Lanka. Fifty-one percent, however, thought that rapid population growth or large family size could hamper economic development. The low levels of knowledge may be due to the fact that the in-school program was not implemented between 1977 and 1980 even though general information, which may have influenced attitudes, was circulated through mass media and out-of-school programs.

### Behavioral Changes

Whether population education should be expected to change fertility-related behavior is a debatable question. Courses such as mathematics, social studies, and home economics are not evaluated in terms of changing student behavior, especially specific actions after leaving school. In fact, only a few courses of a very practical nature, for example, drivers' education for adolescents, have been evaluated to show a measurable influence on later behavior (203).

On one hand, many educators argue that population education should not be evaluated in terms of changing fertility because it is a large and complex subject (40, 163, 180, 338, 365). Some would separate population education entirely from family planning programs. The goals of population education would be set in terms of educational objectives such as gaining knowledge, understanding, and skills rather than in terms of behavioral objectives (see p. M-211).

On the other hand, many of the governments that have established population education programs have done so in support of explicit national policies to reduce population growth. Much of the international support for population education has been provided for the same reason. Donor agencies often expect programs to show quantitative results in terms of mortality, morbidity, birthrates, or contraceptive use. Public health or family planning programs tend to be rigorously evaluated, and the results, widely distributed, so that policymakers and funding agencies can find out whether the programs do in fact make a difference.

This can create a conflict of priorities. Population agencies with limited funds may be reluctant to support programs such as in-school education that do not show a quick, measurable, and cost-effective impact on fertility. Educators, for their part, may be reluctant to use scarce educational resources to introduce a new subject that is potentially controversial and may be intended to support government population policies more than to meet the goals of the educational system. Maintaining interest and support for population education in the face of these different and sometimes competing concerns is a challenge.

### Improving Population Education

Clearly it is too early to offer any final assessment of population education programs in the formal school system. Nevertheless, at least two basic points should be kept in mind in evaluating such programs. First, as extensive international evaluation of education programs has shown, the low quality of schooling remains a problem in many developing countries (357). The difficulties that have plagued population education programs have been found in every other area of education. These difficulties include: teachers who are not adequately trained; classroom teaching materials that are in short supply and of poor quality; and content that is poorly presented and difficult for students to understand (357).

No one would argue that, because of these deficiencies, schools should be abolished. No one would argue that, because children score low on exams in reading, writing, or arithmetic, these subjects should be dropped. If population problems are a serious concern—as they are in many parts of the world—they should be considered in the school curriculum. What is necessary is to find the best and most cost-effective ways to present these issues in a school setting. To do so requires more and better evaluation of existing approaches. Such evaluation is necessary—not to find out whether population topics should be included—but rather to find out how to include them more effectively, so that teachers and students both will be able to understand, to discuss, and to act rationally and responsibly on issues that are important to them, to their communities, and to their countries.

## Table 2. Current Status and Major Characteristics, Selected New or Small Population Education Programs and Projects

| Region, Country, & Ref. No. | History & Current Status | Government Population Policy & Year Adopted[1] | Participating Agency(ies) | Curriculum |  |  | Personnel Training | Materials Development | Evaluation[2] |
|---|---|---|---|---|---|---|---|---|---|
|  |  |  |  | Content Emphasis | Grade Levels | Subjects Used |  |  |  |
| **ASIA & PACIFIC** |  |  |  |  |  |  |  |  |  |
| **China, People's Rep. of** (58, 263, 310) | Implementation began, 1980; expected completion, 1982. | A 1962 | First Department of General Education of Ministry of Education | Importance of family planning and late marriage | 7–8 | Biology, geography, hygiene, physiology, political study | 10-day courses for administrators; some middle school teachers to receive one-month in-service training. | Audiovisual aids, reference materials, teaching materials for 10 pilot schools | NA |
| **Fiji** (220, 266, 270, 278) | Some population concepts in primary school curriculum | A 1962 | Curriculum Development Center of Ministry of Education | Population trends and effects, family planning, human reproduction, population and ecology, family life | 9–12 | Basic science, social science | NA | NA | NA |
| **India** (85, 278, 279) | NCERT[3] workshops and curriculum study since 1970; UNFPA funding since 1980. | A 1952 | Education department in each state, with help from Population Education Cell of NCERT | Population trends and effects, family life | All (planned) | Pilot efforts in all subjects | Varies by state | Student workbooks, reference materials, audiovisual aids, teachers' manuals (materials vary by state) | Curriculum surveys, 1973 (154), surveys of student knowledge, attitudes, 1975 (196), 1977 (328); UNFPA needs assessment, 1979 (293); tripartite review, 1981 |
| **Nepal** (159, 160, 304) | Textbook revision in mid-1970s incorporated some population concepts; UNFPA funding since 1981. | A 1966 | Tribhavan University (Institute of Education and Curriculum Development Center); Curriculum, Textbook, and Supervision Development Center of Ministry of Education | Population trends and effects, family planning | Planned for:<br>1–3<br>4–7<br>8–10 | Arithmetic, language, social studies<br>Social studies<br>Geography, health, home science | Orientation seminars for project staff | Instructional units for teacher-trainers in preparation | UNFPA needs assessment, 1979 (305); national survey of attitudes and awareness, 1981. |
| **Pakistan** (56, 257, 266) | Initial study, 1971–72; seminar, 1973; some population concepts since integrated into curriculum; major program planned. | A 1960 | Population Education Cell in Ministry of Education | Population trends and effects | 1–10 | Geography, health education, home economics, mathematics, social studies | In-service teacher training by correspondence course | Sourcebook, teachers' manual | UNFPA needs assessment, 1979 (373) |

Table 2. continued

| Region, Country, & Ref. No. | History & Current Status | Government Population Policy & Year Adopted[1] | Participating Agency(ies) | Curriculum | | | Personnel Training | Materials Development | Evaluation[2] |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Content Emphasis | Grade Levels | Subjects Used | | | |
| **Papua New Guinea** (270, 272) | Some population concepts already in syllabus; major program planned. | B 1968 | Population Action Program in Office of Environment and Conservation | Population trends and effects | 2–6 | Community life | NA | NA | NA |
| | | | | | 9 | Ecology | | | |
| | | | | | 10 | Social science | | | |
| | | | | | 12 | Science | | | |
| **AFRICA & MIDDLE EAST** | | | | | | | | | |
| **Egypt** (111, 133, 134, 292) | Curriculum planning and development began in early 1970s. Some donor funding since late 1970s. | A 1965 | Office of Population and Environmental Education in Ministry of Education | Population trends and effects | Planned for 1–12 | 7 subjects | Five 7–10 day teacher workshops, correspondence course | Teachers' manuals, model lesson plans | Assessment of population content in textbooks, early 1970s; evaluations of teacher workshops, 1978–1982 (108, 111, 126, 147); UNFPA needs assessment, 1981 (292). |
| **Ghana** (13, 52, 143) | In development since 1972 | A 1969 | Ghana Home Science Association; Ministry of Education | Family planning and family life education | In pilot stage at 9 schools | Home economics | Home economics curriculum in all training institutions for secondary-level teachers include family planning concepts. | Syllabus for secondary level home economics, in pilot stage | NA |
| **Kenya** (299, 344) | In development since 1972 | A 1966 | Christian Council of Kenya | Family life, human reproduction | Syllabus for teachers of grades 4–11 | NA | Some inservice courses for teachers | Family life syllabus | UNFPA needs assessment, 1979 (299) |
| **Mauritius** (166, 514) | Mauritius Family Planning Association has promoted population education in schools since 1970. | A 1965 | Mauritius Family Planning Association; Institute of Education | Population trends and effects | Primary | Home economics, integrated science, social studies | One-term course in population and family life at Institute of Education | Booklet for students | NA |
| **Somalia** (91, 92, 283) | Implementation began, July 1981 | C[4] | Ministry of Education | Population trends and effects | Planned for 1–6 | Health, hygiene, science, social studies | First seminar for primary level teacher-trainers being planned. | Primary-level modules in development | UNFPA needs assessment, 1979 (316); tripartite review, 1981. |
| | | | | | 7–10 | Biology, geography | | | |

Table 2. continued

| Region, Country, & Ref. No. | History & Current Status | Government Population Policy & Year Adopted[1] | Participating Agency(ies) | Curriculum | | | Personnel Training | Materials Development | Evaluation[2] |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Content Emphasis | Grade Levels | Subjects Used | | | |
| **Yemen, People's Democratic Rep.** (173, 174, 284) | National curriculum revision project began, 1976; UNFPA funding since 1980. | C[5] | Educational Research Center of Ministry of Education | Population dynamics, family life | Planned for all | Varies by grade | Planned: 2-month summer courses for teacher-trainers; pre-service training and evening in-service training | Primary- and secondary-level texts with integrated population content in development | UNFPA needs assessment, 1978 (309) |
| **LATIN AMERICA** | | | | | | | | | |
| **Chile** (38, 280, 282) | Educational reform in 1966 introduced population education; large-scale program designed in 1978–79 not approved by government; program ended, 1979. | C 1979 | Ministry of Education | Population dynamics | 10 & 12 | Social studies | Some training seminars for teachers | Teachers' manuals | UNESCO-sponsored evaluation, 1975 |
| **Colombia** (30, 32, 45, 70, 175, 281, 369) | Initial experimental program, late 1960s, implementation with UNFPA funding, 1972–1976; post-project activities through 1980. (In Cauca Valley region) | A 1970 | Valle University Center for Population Research (CUIP), with support from Ministry of Education | Population trends and effects, family life, environment, sex education | 3–11 | All | Summer courses for teachers | Teachers' manuals, student modules | Survey of student knowledge and attitude change, 1967–1968 (30, 32) |
| | Teacher training in family and sex education, 1979 (300 teachers in Bogotá) | | Colombian Association for the Study of Population (ACEP) | Family and sex education | | | One-week seminars | Teachers' manual | NA |
| **Dominican Republic** (70, 214, 281, 288, 291) | Conceived and funded, 1978; implementation began, 1979. | A 1968 | Population Education Project in Secretariat of Education, Fine Arts, and Culture | Sex education, family life education, ecology, demography | 1–6 | Natural science, social science | Workshops for school principals, who then trained teachers; pre-service training at 6 teacher training institutes. | Teachers' manuals, 4 teaching units for primary school teachers | Tripartite review, 1980 |

**Table 2. continued**

| Region, Country, & Ref. No. | History & Current Status | Government Population Policy & Year Adopted[1] | Participating Agency(ies) | Curriculum: Content Emphasis | Curriculum: Grade Levels | Curriculum: Subjects Used | Personnel Training | Materials Development | Evaluation[2] |
|---|---|---|---|---|---|---|---|---|---|
| **Mexico** (11, 46, 47, 48, 49, 60, 287) | Some population concepts integrated into texts during curriculum revision, early 1970s; sex education program funded by SIDA,[6] 1976–1980. | A 1974 | National Population Council (CONAPO) | Family, population, and sex education | 1–12 | Language, mathematics, natural science, social science | Several-day workshops for teachers | School texts with integrated sex, family, and population material; teachers' manuals. | NA |
| **Paraguay** (170, 281) | Implementation began, 1980 | B 1972 | Ministry of Education and Worship | Family education | In planning | In planning | Month-long courses for teacher-trainers planned | NA | UNFPA needs assessment, 1979 (308); survey of attitudes and family patterns, 1980. |
| **NORTH AMERICA** | | | | | | | | | |
| **Baltimore, US** (42, 67, 181) | Started, 1971; established part of curriculum since 1975. | B 1970 | Urban Life Population Education Institute in Baltimore City school system | Population trends and effects, family life, urban life issues | 6 & 9<br>9<br>10 or 11 | Social studies<br>Home economics<br>World cultures | 1–3 day workshops for teachers | Four comprehensive units | Assessments of teacher training, 1974 (67); study of student achievement and attitudes, 1978 (181). |

Note: For information on funding of some of these programs, see Table 3, pp. M-235–237.
NA = not available

[1] National government population policy from Nortman & Hofstatter (161) except where otherwise noted.
A = government policy is to reduce population growth rate
B = government supportive of family planning for nondemographic reasons
C = government policy either neutral or pronatalist

[2] Includes evaluation of program impact, tripartite reviews, preprogram assessments, and UNFPA needs assessment missions. Tripartite reviews are joint UNFPA, UNESCO, and host-country agency evaluations of how well a program is progressing towards its established goals. UNFPA needs assessments are 2-week visits by UNFPA staff and consultants to establish the current status and projected needs of population programs, including population education.

[3] NCERT = Indian National Council of Educational Research and Training

[4] Source: UN (283). Information concerning year policy adopted not available.
[5] Source: UN (284). Information concerning year policy adopted not available.
[6] SIDA = Swedish International Development Authority

## Table 3. External Funding of Selected In-School Population Education Activities

| Region, Country & Ref. No. | Amount of External Funding (in $US), Source, Years, and Activities Funded |
|---|---|
| **ASIA & PACIFIC** | |
| **Bangladesh** (134, 217, 289) | $1,140,000 UNFPA 1975–1985[1]<br>Training—one-week seminars for 66,000 primary, secondary, and Madrasah (religious) school teachers and 1,000 university instructors. Some materials development. |
| **China, People's Rep. of** (217, 310) | $500,000 UNFPA 1980–1982<br>Training—one-month courses for 8,000 middle school teachers. Equipment—modern audiovisual facilities and reference books for 10 teacher training institutes; modern audiovisual aids, books, and instructional materials for 10 middle schools. Revise middle school curriculum. |
| **India** (85) | $5,322,000 UNFPA 1980–1983<br>(Programs vary by state. 19 states have own programs; 10 began in 1980, 9 in 1981. Coordination by National Council of Educational Research and Training.) |
| **Indonesia** (133, 215, 217, 278, 295, 296, 297) | $1,300,000 World Bank (loan) 1973–1985[2]<br>Training—2-week courses for 240 secondary-level teacher training institute lecturers. 10-day courses for 900 primary-level teacher training institute instructors. Materials—development and printing of 340,000 textbooks and 85,000 teachers' handbooks. |

**Table 3. continued**

| Region, Country & Ref. No. | Amount of External Funding (in $US), Source, Years, and Activities Funded |
|---|---|
| **Indonesia continued** | $48,000 UNFPA 1977–1981<br>Training for personnel involved in coordination of projects. |
| | $157,000 UNFPA; $390,000 Sirami, Church World Service, Oxfam, World Neighbors, Asia Foundation, Family Planning International Assistance 1978–1981<br>For schools of the Council of Churches. Training—one-week seminars for 150 master teachers[3] and teacher-trainers; one-day sessions for teachers in 1,100 primary and 600 secondary schools. |
| | $120,000 UNFPA 1978–1981<br>For schools of the Muhammidayah (an Islamic movement). Training—one-week seminars for 150 master teachers. 3-day courses taught by master teachers for 8,000 primary and secondary school teachers. Materials—one set of prototype materials for each of 4,300 primary and 2,000 secondary schools. |
| | $223,000 UNFPA 1979–1981<br>For schools and institutes of Islamic Education and Higher Education. Pilot project—development of curricular materials and training seminars for 200 teachers in 5 provinces of Java. Pilot project in some teacher training schools. |
| **Korea, Rep. of** (217, 246) | $1,520,000 UNFPA 1973–1981<br>Training—3-day sessions for 6,800 high school teachers and 4,500 middle school teachers. Development of pre-service training programs at 11 junior teachers colleges and 15 colleges of education. (Numbers are those actually trained. Original plan for 5-day courses for 15,000 secondary and 35,000 primary school teachers proved not feasible.) |
| **Malaysia** (217, 300) | $1,045,000 UNFPA 1973–1983[1]<br>Training—80,000 middle school teachers, using SLEMs. |
| **Nepal** (217, 304) | $655,000 UNFPA 1980–1983<br>Training—7,750 lower secondary and secondary school teachers through face-to-face instruction and radio programs. |
| **Philippines** (176, 177, 217, 246) | $1,575,000 UNFPA 1972–1980[1]<br>Training—208,000 primary and 10,000 secondary level teachers by national supervisory training teams. Materials—variety of guides, references, and instructional materials to be distributed to all teachers concerned. Limited distribution of student reference books. (SLEMs and middle-level trainers used because of inadequate progress of training teams. Student materials limited by funds.) |
| | $600,000 (approx.) UNFPA 1982–1983[1]<br>Regionalization project: Training—orientation sessions for 1,000 regional and divisional personnel and school principals; courses for 256 master trainers who will in turn train 2,000 assistant principals and department heads. These will in turn train 10,000 secondary-level teachers. Materials—production and distribution of the following secondary-level materials adapted or specifically developed for use in 13 educational regions: 15,000 teachers' manuals, 1,500 sets of training modules. |
| **Solomon Islands** (223) | $44,000 UNFPA 1981–1982<br>Awareness seminars for national and provincial policy-makers. Development and distribution of curricular materials. Introduction of population education into regular in-service teacher training. |
| **Sri Lanka** (215, 217, 278) | $478,000 UNFPA 1973–1985<br>Training—24,000 teachers. Materials—national sourcebook. |
| **Thailand** (200, 217, 231, 244, 274, 298, 319) | $268,000 UNFPA 1972–1975<br>$90,000 Rockefeller Foundation 1976–1979<br>Mahidol University project: Training—some in-service seminars; pre-service population curriculum developed and instituted. Masters degree in population education offered. Curricular materials developed. Research in population education. (Project funding included out-of-school elements as well (i.e., extension worker training and materials development).) |
| | $1,326,000 UNFPA 1978–1985[1]<br>Training—13,000 teacher-trainers. Materials—at least one set of teachers' manual, curriculum guide, and other materials for each school. (Includes out-of-school component.) |
| **Trust Territory of the Pacific Islands** | |
| **Marshall Islands** (323) | $45,000 UNFPA 1981–1982<br>Seminars for policy-makers, teachers, education officials, and local leaders to promote awareness of population education. Development of prototype curricula and instructional materials and their introduction on a pilot scale. Acquisition of material for libraries of selected schools and the Education Ministry. |
| **Micronesia** (322) | $50,000 UNFPA 1981<br>Seminars for education, church, and community leaders in all 4 states. National seminar for participants in state seminars to share experiences, assess needs, and make recommendations for national plan. Acquisition of materials for libraries of state and national education departments and selected schools. |
| **Palau** (321) | $30,000 UNFPA 1981–1982<br>Village surveys of population-related problems. Training—seminars and workshops, using survey results, to integrate population content into existing school subjects. |
| **AFRICA & MIDDLE EAST** | |
| **Benin** (52, 217, 242) | $150,000 UNFPA 1976–1980<br>6 regional seminars and publication of reports of seminar findings. |
| **Egypt** (133, 134, 366) | $408,000 World Bank (loan) 1980<br>Training—pre-service training for secondary school teachers. Materials—audiovisual materials for training sessions. Foreign consultants—one long-term, two short-term. (Egyptian government to fund much of teacher training and materials production.) |
| | $45,000 USAID 1977–1981<br>Workshops for project personnel and teachers. |
| **Ivory Coast** (52, 217) | $21,000 UNFPA 1977<br>National seminar to examine problems and needs. |
| | $17,000 UNFPA 1980<br>National seminar for educators to assess trends in population shown in recent census results. Training—2 overseas graduate fellowships and study tours of Tunisian population education program. |
| **Morocco** (302) | $454,000 UNFPA 1981–1983<br>Training—3-day seminars for project personnel, supervisors, and teachers. Equipment—audiovisual equipment, vehicles, and office equipment. |
| **Nigeria** (217, 242) | $51,000 UNFPA 1981<br>Evaluation of needs and organizational activities in preparation for national program. |

**Table 3. continued**

| Region, Country & Ref. No. | Amount of External Funding (in $US), Source, Years, and Activities Funded |
|---|---|
| **Sierra Leone**<br>(217, 314) | $337,00 UNFPA 1977–1982[1]<br>Training—1,330 secondary school teachers. Materials—2 secondary school textbooks and one textbook supplement developed. (Distribution limited.) |
| **Somalia**<br>(91, 92, 215, 217) | $341,000 UNFPA 1981–1982<br>Training—2 overseas graduate fellowships; one-semester training courses in Cairo, Egypt, for 20 participants; study tours for 10 teachers. Materials—primary school teaching modules and national sourcebook. |
| **Sudan**<br>(217, 317) | $236,000 UNFPA 1980–1983<br>Training—180 teacher-trainers, 60 primary school supervisors, 60 secondary school supervisors, 60 secondary school teacher training institute supervisors. |
| **Tunisia**<br>(215, 217, 246) | $738,000 UNFPA 1974–1982<br>Training—1,500 secondary school teachers and principals. Materials—6 teachers' manuals. |
| **Upper Volta**<br>(52, 217, 218, 242) | $59,000 UNFPA 1976<br>Training—seminar on population and sex education for national officials in education, health, information, rural development, and economic planning. (Subsequent activities primarily in sex education.) |
| **Yemen, People's Democratic Yemen, People's Democratic Rep. of**<br>(173, 174, 217) | $281,000 UNFPA 1979–1981<br>Training—pre- and in-service training for 290 primary and secondary school teachers each year. Materials—partial subsidy for printing 120,000 primary and 20,000 secondary school textbooks. Equipment—audiovisual and office equipment, one vehicle. |
| **LATIN AMERICA & CARIBBEAN** | |
| **Chile**<br>(38) | $428,000 UNFPA (Funds requested and approved, 1979)<br>(Planning ended in 1979 as a result of strong pronatalist position taken by government; no funds spent.) |
| **Colombia**<br>(45, 175, 217) | $224,000 UNFPA 1972–1974<br>Valle University project<br>Training—key staff and 164 primary and secondary school teachers. (As a result of this project, some population concepts were included during primary and secondary curriculum reform, 1976).<br>$34,000 UNFPA 1979<br>Training—one-week courses for 300 teachers from Bogotá. Materials—teachers' manual developed, 300 copies printed. |
| **Dominican Republic**<br>(214, 217, 291, 364) | $177,000 UNFPA 1979–1982<br>Training—1,226 trainers. Materials—6,000 first-grade units, 4,000 second-grade units, 3,000 third-grade units, 10,000 teachers' guides printed and distributed in 1980–1981. |
| **El Salvador**<br>(213, 217, 246) | $410,000 UNFPA 1971–1980<br>Curriculum revision and several seminars for teachers. |
| **Nicaragua**<br>(306) | $309,000 UNFPA 1981–1983<br>Training—in-service training for 55 middle-level trainers, 400 primary-level teachers, 100 secondary-level teachers, 150 teacher training school instructors. |
| **Paraguay**<br>(170, 217) | $417,000 UNFPA 1980–1983<br>Training—13,000 primary and 2,000 secondary school teachers to be trained by national supervisory training teams. Materials—population education kits for all teachers trained. |

Note: For more information on some of these programs, see Table 1, pp. M-205–206 and Table 2, p. M-232–235.

UNFPA = United Nations Fund for Population Activities
SLEM = Self-Learning Educational Module
USAID = United States Agency for International Development

[1] In addition to UNFPA funding, project or activity has received assistance through a population education component of a larger population or education project of the World Bank (134). Specific information not available.

[2] World Bank loans generally are fully disbursed within five years of project agreement. Indonesia has received funding under three consecutive population projects (134).

[3] A master teacher is a teacher from a particular school responsible for training all teachers in that school (i.e., a peer trainer) or a teacher of a particular subject responsible for training all the teachers of that subject in the district or region.

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ORAL CONTRACEPTIVES

Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

# Oral Contraceptives in the 1980s

**Editors' Summary.** More than 50 million women around the world are using oral contraceptives (OCs) as of 1980-81. Over half of these women buy supplies from pharmacies or other commercial sources, with or without a medical prescription. The rest, including about 7 million Chinese women, are supplied by government or private sector programs.

In developed countries, where almost all users buy their OCs, sales fell from a peak of about 287 million cycles in 1975 to 253 million in 1979 and have remained stable at that level. The major drop in sales took place in the US. By contrast, sales in a number of Latin American countries have increased by about 50 percent since 1975. In other developing areas public and private family planning programs supply all but a small percentage of users. The US Agency for International Development (USAID) provides family planning programs, mostly in Asia, with about 100 million cycles annually. Other donors and international agencies altogether provide about 20 million cycles annually.

Knowledge of the benefits and risks of the pill has grown considerably in recent years. Important health benefits of OC use have been identified in addition to prevention of unwanted pregnancy. At the same time it has become clear that the risks associated with OC use are largely confined to women over age 35 and especially to women over 35 who smoke. The risk for younger women is very small.

### Beneficial Effects Noted

The benefits of OC use cover a wide range of health concerns, beginning, of course, with effective contraception. US surveys show that the pill is the most effective reversible means of preventing unwanted pregnancy. By comparison, IUDs have a 12-month failure rate two times greater than the pill, condoms three times, diaphragms four times, and other methods more than five times greater. Of course, the effectiveness of OCs depends on regular use.

Among the other beneficial effects that some women obtain from OC use are:

- Protection against pelvic inflammatory disease (PID). Current OC users face about half the risk of noncontraceptors or one-fourth the risk of IUD users. PID can lead to later infertility or ectopic pregnancy as a result of blocked tubes.
- Protection against ectopic pregnancy. Current OC users have one-tenth the risk of noncontraceptors of developing *ectopic, or extrauterine,* pregnancy. Ectopic pregnancy can be a life-threatening emergency that requires immediate surgery.
- Protection against endometrial cancer. Women who have used OCs for a year or more have about one-third the risk of never users of developing this form of uterine cancer.
- Protection against cancer of the ovaries. Women who have used OCs face about two-thirds the risk of never users of developing ovarian cancer.
- Protection against benign breast disease. Current OC users have breast lumps or cysts about half as often as nonusers. Benign breast disease is very common in developed countries and may require repeated biopsy to rule out cancer.
- Relief from a wide range of common menstrual disorders, including irregular menses, premenstrual tension, excess blood loss (which may lead to anemia), and cramps.

Recognizing the importance of these benefits, the United States Food and Drug Administration's Committee on Fertility and Maternal Health recommended in February 1982 that instructions in each pill package include information on the benefits of OC use.

### Risks Limited

In the last half decade three major cohort studies and a number of other analyses have found that the greatest danger associated with pill use is increased risk of circulatory system disease among women over 35, especially women who smoke. In the largest study, conducted by the Royal College of General Practitioners in Britain and involving nearly 50,000 white women, a pattern emerged. Among all women under age 35 and among nonsmokers under 45, there were no statistically significant differences between OC users and nonusers in the rates of death from circulatory system disease. Among older women risk was lowest for those who neither smoked nor used OCs, somewhat higher and roughly equal for those who either smoked or used OCs, and much higher for those who both smoked and used OCs. Risks are reduced with lower doses.

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Volume X, Number 3

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Phyllis T. Piotrow, Ph.D., Director; Walter Stender, Associate Director; Ward Rinehart, Editor.

It is generally agreed that OC use increases the risk of four specific conditions among the US and British women who have been studied:

- venous thromboembolism, or blood clots in the veins,
- ischemic heart disease, including heart attack,
- cerebrovascular disease, or stroke,
- hypertension, or high blood pressure.

The most serious risks are heart attack and stroke.

The Royal College study found that, overall, OC users were four times more likely to die of circulatory system disease than nonusers, but it is debatable how overall figures apply to other populations or individual women. Deaths in all of the cohort studies are concentrated among older women who smoke. The number of deaths in younger women is so few that no conclusions can be drawn from them. Analyses of national rates of death from circulatory system disease in a number of countries suggest that the overall estimates of mortality risks are not applicable to most OC users. Also, it is not clear whether they apply only to white women or to other ethnic groups as well. Whether these estimates of risk apply in developing countries is even less certain. More research is necessary to determine whether problems seen in developed countries occur in developing countries and whether there are problems in developing countries that have not been seen in developed-country women. So far no serious new problems have been found in developing countries.

### Other Effects Minimal

Apart from benefits associated primarily with reproductive functions and organs and risks associated primarily with the circulatory system, other health effects of OCs appear to be rare or of little clinical importance.

When OCs were first introduced in the early 1960s, some scientists were afraid that they might increase the risk of breast cancer, already the most common cancer among women in developed countries. Breast cancer has a long latent period, but to date, after more than 20 years of experience, no increase with OC use has been demonstrated. While the evidence is inconclusive, OCs have not been proved to influence rates of cancer of the cervix, melanoma (skin cancer), or pituitary tumors. OCs are associated with the occurrence of nonmalignant liver tumors in one or two per 100,000 women per year. These tumors may rupture, causing internal bleeding and possibly death.

OCs have no adverse effects on later childbearing. Return of fecundity is delayed by several months in some OC users, but fecundity does not appear to be permanently impaired. Rates of miscarriages and birth defects are not affected by OC use before pregnancy, although some questions remain about birth defects and inadvertent OC use during pregnancy. In breast-feeding mothers, OC use may reduce the volume of milk or duration of breast-feeding, but use of OCs with 50 mcg or less of estrogen has not been shown to affect infant growth.

### Benefits of Regular Use Outweigh Risks

An objective assessment of the risks and benefits of using OCs must take into account the risks of pregnancy if contraception is not used and the availability and risks of other contraceptive methods. In both developed and developing countries the risks associated with pregnancy and childbirth are much higher than those associated with using OCs. For most women in developing countries using OCs for a year is much less dangerous than using no contraception for a year and risking pregnancy. Even for the few developing-country women over age 35 who smoke, the hazards of OC use do not approach the hazards of pregnancy if contraceptives are not used. For this group especially, however, other methods of fertility control would be safer than OCs.

Under existing conditions in developing countries, the pregnancies that occur because of irregular use of the pill—or of other methods of family planning—cause more deaths than the methods themselves. The implications for family planning programs are clear: Older women who smoke should be encouraged to use a method other than the pill or to stop smoking. For younger women and nonsmokers, encouraging regular use of OCs will yield greater health benefits than restricting the availability and use of OCs. Greater effort is needed not only to make reversible means of contraception such as OCs widely available, but also to be sure that they are used regularly and correctly so that women obtain their full benefit.

**End of Editors' Summary.**

### Reviews Find OC Risks Down, Benefits Up

Oral contraception is now 20 years old. Recent authoritative reviews suggest that for most women the risks of OC use, especially with current lower dose formulations, are less than previously thought, and new benefits are becoming clear. These reviews include:

- *Oral contraception today: three dialogues.* Journal of Reproductive Medicine 27(4, Suppl.): 235–295. April 1982.
- *Twenty years progress in oral contraception.* Acta Obstetricia et Gynecologica Scandinavica (Suppl. 105). 1982. 105 p.
- World Health Organization. *Oral contraceptives: technical and safety aspects.* Geneva, 1982. 42 p.
- Ory, H.W., Rosenfield, A., and Landman, L.C. *The pill at 20: an assessment.* International Family Planning Perspectives 6(4): 125–130. December 1980.

## USAGE

Over 50 million women throughout the world are using oral contraceptives today. Users in developing countries (excluding China) increased from about 14 million in 1977 to 18 million in 1980. The number in China, now estimated at about 7 million, probably decreased during the late 1970s, but reliable data are not available. Use in developed countries, including both commercial sales and government programs, is at about the same level as in 1977—28 million women.

Several kinds of information can be used to assess OC use:

- commercial sales data,
- family planning program service statistics,
- donor agency records,
- sample surveys of women of reproductive age,
- estimates of Chinese practices provided by officials and visitors to China.

### Commercial Sales

Data on commercial sales in many countries are compiled by Intercontinental Medical Statistics Ltd. (IMS) from purchase invoices gathered from a representative sample of pharmacies in each country. IMS data for 14 developing areas and 18 developed areas show a total of 334 million cycles sold in 1980. Sales in the developing countries covered by IMS have increased every year and in 1980 amounted to nearly 76 million cycles. Sales in developed countries reached a peak of 287 million in 1975, fell to 253 million in 1979, and are remaining relatively stable at that level. (See Table 1.)

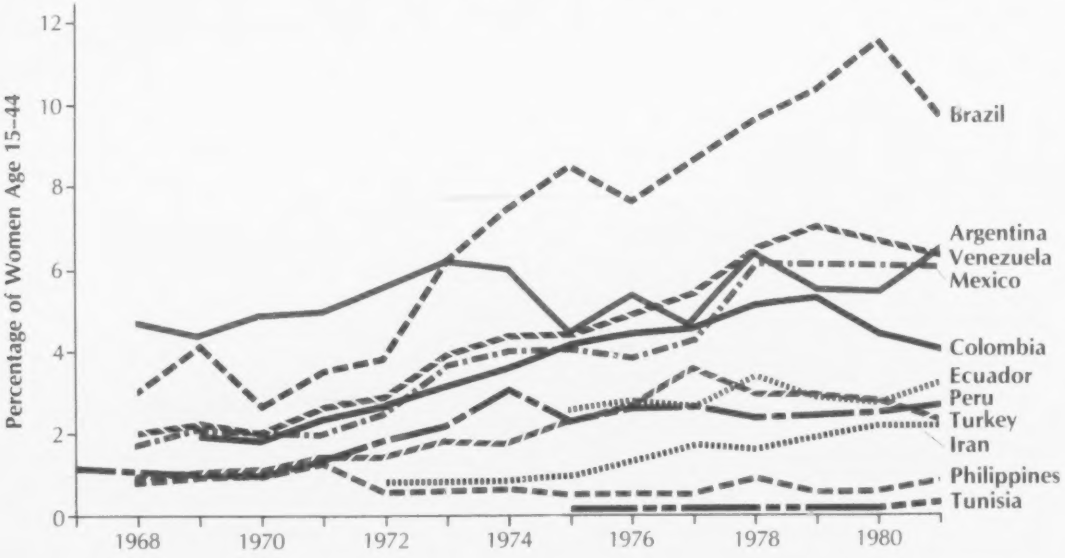
IMS data cover the major commercial markets but do not cover most Asian, Eastern European, Middle Eastern, and African countries, including a few, such as Hong Kong, Singapore, and East Germany, where OC use is high. Data include both prescription and nonprescription sales but not purchases by hospitals or clinics, donations, free samples, or subsidized marketing projects.

IMS sales data can be used to estimate the number of women supplied through regular commercial channels. This can be done by dividing the number of cycles sold annually by 13—the number of cycles needed by one woman for a year. The resulting figure is a conservative estimate of the number of users at any one time because it assumes that each woman takes pills for a full year.

Two of the largest increases in developing country sales over the last decade occurred in Brazil and Mexico. In Brazil commercial sales increased from 7 million cycles in 1970 to 41 million in 1980, enough in 1980 to supply 12 percent of all women age 15-44 for one year (see Figure 1). In Mexico sales increased from 3 million cycles in 1970 to 12 million by 1980, enough for 6 percent of women age 15-44. This calculation for Mexico probably represents about half of total use, since another 10 million cycles were supplied to Mexican family planning programs by donor agencies.

The highest levels of OC use calculated on the basis of IMS sales data are in Australia, Austria, Belgium, France, West Germany, the Netherlands, and New Zealand, where over 20 percent of all women of reproductive age purchase orals (see Figure 2). US use decreased from a maximum of about 17 percent of all women of reproductive age in 1974 to about 10 percent in 1981. Another IMS survey, which projects the number of times physicians started or continued their patients on oral contraceptives, shows that in the US the decline is greatest among older women. During 1976-1979 there was a 12 percent decline for women age 20-24, a 30 percent decline for women age 25-34, 52 percent for age 35-39, 58 percent for age 40-44, and 70 percent for age 45-49 (498). The sharp drop among

**Figure 1. Minimum Percentage of Women Age 15-44 Supplied with Oral Contraceptives through Commercial Channels in 11 Developing Countries, 1967-1981**



Source: Data for 1967-1969 from **Population Reports**, *Oral Contraceptives—50 Million Users*, A-1, April 1974. Data for 1970-1981 calculated from Table 1. All data based on IMS International/America, Ltd., studies prepared for the Population Information Program, 1973, 1977, 1978, and 1981. (240-242)

**In 11 developing countries where IMS collects data, an increasing percentage of women buy oral contraceptives through commercial channels. Commercial sales in Brazil now supply a larger percentage of all women of reproductive age than they do in the United States.**

### Table 1. Pharmacy Purchases of Oral Contraceptives in Selected Areas, by Country and Year, 1970–1981

(in thousands of cycles)

| | 1970 | 1971 | 1972 | 1973 | 1974 | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | Jan.-June 1981 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **DEVELOPED AREAS** | | | | | | | | | | | | |
| **Australia** | 6,815.7 | 8,191.3 | 8,976.5 | 9,813.8 | 11,983.2 | 12,561.4 | 11,667.8 | 11,056.7 | 9,699.1 | 9,264.1 | 8,866.3 | 4,332.1 |
| **Austria** | 2,174.1 | 2,671.2 | 3,332.0 | 3,743.3 | 3,738.1 | 3,956.2 | 4,316.8 | 4,130.3 | 4,532.0 | 4,460.1 | 4,351.8 | 2,106.1 |
| **Belgium** | 2,996.0 | 3,464.6 | 3,909.8 | 4,957.5 | 5,563.9 | 6,796.5 | 7,141.0 | 7,471.0 | 7,926.9 | 7,945.9 | 8,196.5 | 4,272.3 |
| **Canada** | 14,012.0 | 15,889.0 | 17,117.0 | 13,884.5 | 15,315.0 | 12,952.1 | 13,413.5 | 13,024.0 | 10,472.5 | 12,360.5 | 14,098.5 | 7,195.0 |
| **Finland** | 1,610.7 | 1,782.2 | 1,865.9 | 1,589.0 | 1,527.9 | 1,507.0 | 1,629.9 | 1,703.9 | 1,555.4 | 1,492.3 | 1,492.4 | 756.4 |
| **France** | 8,231.0 | 11,833.9 | 15,299.0 | 21,495.9 | 27,221.1 | 31,133.9 | 33,796.4 | 35,088.7 | 37,748.0 | 37,863.2 | 39,118.4 | 20,137.7 |
| **Germany, Fed. Rep.** | 29,369.9 | 37,879.1 | 42,901.1 | 45,746.0 | 45,833.5 | 47,178.6 | 48,950.0 | 44,220.2 | 44,458.5 | 46,215.5 | 46,761.1 | 23,295.8 |
| **Greece** | 226.9 | 277.1 | 286.9 | 271.0 | 266.9 | 364.0 | 367.8 | 383.3 | 412.5 | 409.3 | 488.4 | 201.2 |
| **Ireland** | 151.5 | 228.8 | 334.4 | 657.8 | 805.6 | 623.5 | 671.6 | 637.1 | 561.5 | 603.1 | 542.1 | 284.8 |
| **Italy** | 1,808.8 | 2,231.2 | 3,677.4 | 4,268.2 | 5,334.2 | 6,431.1 | 7,625.6 | 8,438.6 | 8,379.7 | 7,783.0 | 7,340.9 | 3,536.4 |
| **Japan*** | 1,042.6 | 1,368.2 | 1,911.9 | 2,804.4 | 4,450.2 | 4,135.7 | 3,708.7 | 3,180.3 | 3,393.6 | 2,176.9 | 1,700.2 | 730.5 |
| **Netherlands** | 6,518.0 | 7,760.0 | 10,149.6 | 11,998.5 | 13,959.9 | 15,204.6 | 15,693.9 | 15,749.2 | 14,981.3 | 13,796.1 | 12,484.6 | 6,223.6 |
| **New Zealand** | 1,593.6 | 1,896.6 | 1,949.8 | 2,082.3 | 2,381.6 | 2,354.5 | 2,460.9 | 2,052.5 | 2,237.4 | 2,404.9 | 2,407.7 | 1,175.5 |
| **Portugal** | | | | | | 3,040.9 | 3,752.0 | 3,981.0 | 4,141.9 | 4,270.5 | 4,137.4 | 2,266.0 |
| **South Africa** | | | | | | 2,414.0 | 2,246.6 | 2,026.5 | 1,396.7 | 1,833.9 | 1,844.9 | 882.5 |
| **Spain** | 1,823.4 | 2,285.0 | 2,760.0 | 3,753.8 | 4,447.4 | 5,756.8 | 6,146.8 | 7,539.3 | 9,766.2 | 10,476.4 | 12,459.9 | 5,806.7 |
| **United Kingdom** | 13,824.7 | 16,997.9 | 18,948.2 | 21,790.5 | 23,812.5 | 28,163.6 | 28,494.2 | 29,492.9 | 26,381.4 | 23,612.4 | 24,301.1 | 12,316.0 |
| **United States** | 70,655.3 | 81,203.7 | 89,147.2 | 98,327.0 | 102,761.0 | 102,790.0 | 90,690.0 | 77,589.0 | 68,809.3 | 66,314.7 | 67,293.6 | 31,791.7 |
| **Subtotal, Developed Areas** | 162,854.2 | 195,959.8 | 222,566.7 | 247,183.5 | 269,402.0 | 287,364.4 | 282,773.5 | 267,764.5 | 257,353.9 | 253,282.8 | 257,885.8 | 127,310.3 |
| **DEVELOPING AREAS** | | | | | | | | | | | | |
| **Asia** | | | | | | | | | | | | |
| **Indonesia** | | | | | | 792.3 | 931.2 | 1,028.1 | 975.2 | 876.0 | 975.0 | 595.5 |
| **Iran** | | | 596.8 | 615.5 | 639.5 | 866.1 | 1,199.0 | 1,529.4 | 1,561.6 | 1,911.4 | 2,265.1 | 1,162.2 |
| **Pakistan** | | | | | | 166.8 | 216.9 | 218.6 | 217.4 | 246.4 | 268.7 | 153.0 |
| **Philippines** | 982.9 | 755.2 | 623.0 | 745.6 | 798.2 | 697.7 | 697.9 | 740.0 | 982.6 | 781.3 | 883.0 | 607.2 |
| **Saudi Arabia** | | | | | | 560.9 | 328.4 | 473.2 | 701.7 | 783.6 | 1,035.9 | 463.0 |
| **Turkey** | 932.1 | 1,349.5 | 1,484.4 | 1,958.1 | 1,876.5 | 2,461.4 | 3,038.5 | 4,144.1 | 3,521.9 | 3,644.3 | 3,522.4 | 1,543.0 |
| **Subtotal** | 1,915.0 | 2,104.7 | 2,704.2 | 3,319.2 | 3,314.2 | 5,545.2 | 6,411.9 | 8,133.4 | 7,960.4 | 8,243.0 | 8,950.1 | 4,523.9 |
| **Latin America** | | | | | | | | | | | | |
| **Argentina** | 3,406.0 | 3,514.3 | 3,924.3 | 4,306.4 | 4,297.7 | 3,209.1 | 3,863.4 | 3,388.2 | 4,655.9 | 4,149.4 | 4,109.2 | 2,507.7 |
| **Brazil** | 6,895.0 | 9,314.3 | 10,383.2 | 17,966.3 | 22,490.8 | 26,207.4 | 24,320.6 | 28,577.8 | 32,311.6 | 35,812.3 | 40,991.1 | 17,902.6 |
| **Central America** | | | 1,012.8 | 1,112.8 | 1,103.1 | 1,097.7 | 1,249.1 | 1,192.8 | 1,402.6 | 1,352.6 | 1,341.4 | 661.7 |
| **Colombia** | 1,105.0 | 1,404.2 | 1,641.5 | 2,048.3 | 2,417.2 | 2,794.3 | 3,064.1 | 3,328.3 | 3,842.8 | 4,057.8 | 3,507.2 | 1,665.3 |
| **Ecuador** | | | | | | 470.1 | 532.8 | 533.6 | 695.4 | 613.6 | 610.1 | 365.3 |
| **Mexico** | 2,810.0 | 2,715.8 | 3,628.4 | 5,244.6 | 5,974.4 | 6,176.8 | 6,373.5 | 7,244.3 | 10,869.5 | 11,141.9 | 11,513.1 | 5,895.7 |
| **Peru** | 376.0 | 497.6 | 680.3 | 867.0 | 1,203.6 | 986.0 | 1,171.1 | 1,218.5 | 1,052.2 | 1,115.2 | 1,246.2 | 671.2 |
| **Puerto Rico** | 233.0 | 311.0 | 427.0 | 449.9 | 809.0 | 840.3 | 715.2 | 885.8 | 801.9 | 916.0 | 580.1 | 174.5 |
| **Venezuela** | 553.0 | 716.1 | 828.4 | 1,203.7 | 1,361.9 | 1,512.7 | 1,764.1 | 2,000.3 | 2,534.3 | 2,880.0 | 2,854.5 | 1,423.6 |
| **Subtotal** | 15,378.0 | 18,473.3 | 22,525.9 | 33,199.0 | 39,657.7 | 43,294.4 | 43,053.9 | 48,369.6 | 58,166.2 | 62,038.8 | 66,752.9 | 31,267.6 |
| **Subtotal, Developing areas** | 17,293.0 | 20,578.0 | 25,230.1 | 36,518.2 | 42,971.9 | 48,839.6 | 49,465.8 | 56,503.0 | 66,126.6 | 70,281.8 | 75,703.0 | 35,791.5 |
| **TOTAL** | 180,147.2 | 216,537.8 | 247,796.8 | 283,701.7 | 312,373.9 | 336,204.0 | 332,239.3 | 324,267.5 | 323,480.5 | 323,564.6 | 333,588.8 | 163,101.8 |

Note: These figures do not include subsidized programs, samples, or sales to hospitals or family planning clinics.

*Products licensed for therapeutic, not contraceptive purposes

Source: IMS International/America, Ltd., studies prepared for the Population Information Program, 1977, 1978, and 1981 (240–242)

women over 35 almost certainly results from reports of greater risk of pill use for older women, which began reaching the public in late 1975 (267).

## Program Service Statistics

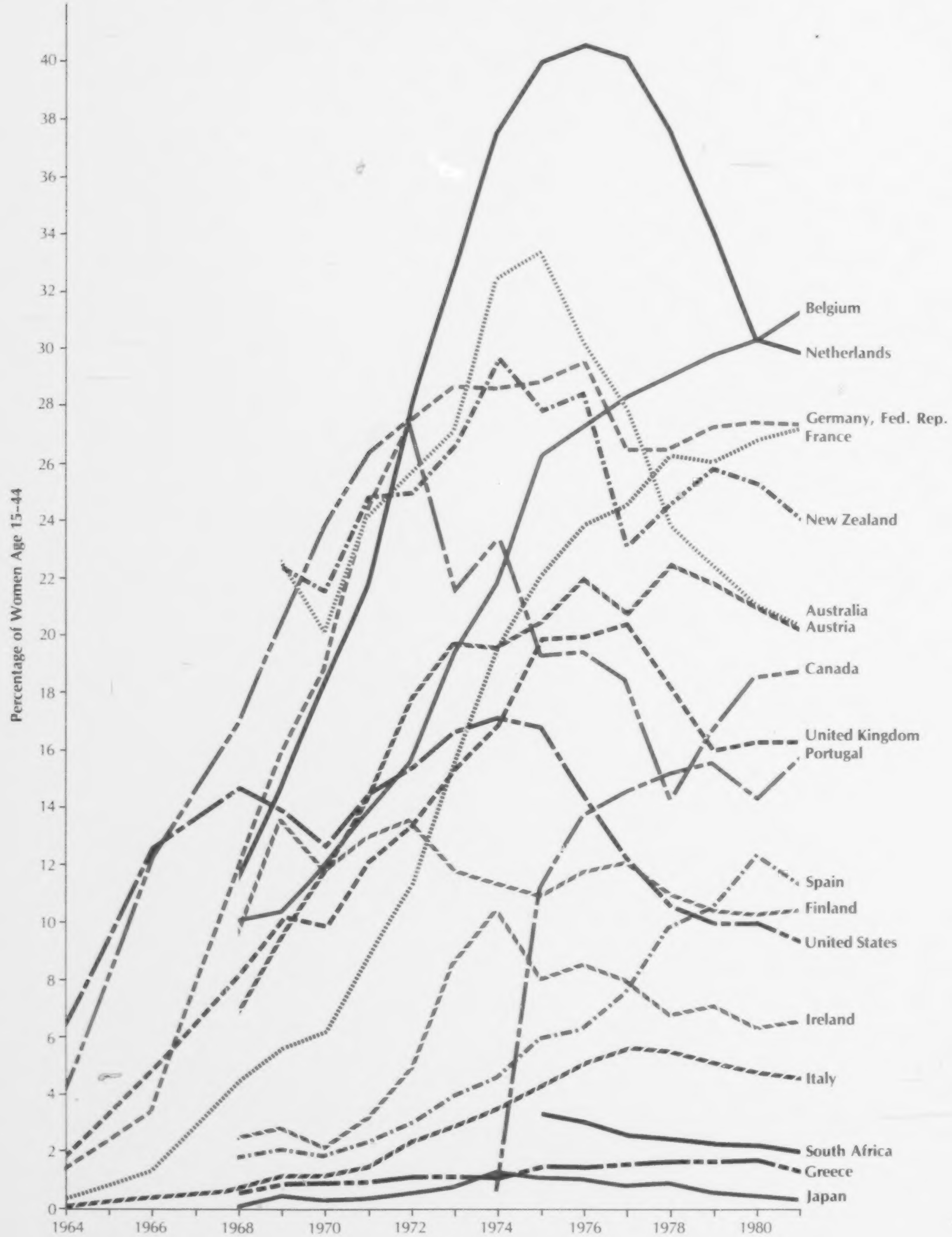
Service statistics from family planning programs also provide information on contraceptive use. Many of these data have been collected by Dorothy Nortman in the most recent Population Council *Factbook* (382). Between 1976 and 1980 the number of new acceptors provided with oral contraceptives through government programs increased in five Asian countries—India, Indonesia, Taiwan, Thailand, and Sri Lanka—and in Mexico. Voluntary sterilization also increased in all these countries except India, where surveys show that about 20 percent of married women of reproductive age are already sterilized. The number of new pill users in Colombia, Costa Rica, Egypt, South Korea, the Philippines, and Singapore decreased (382). In South Korea and Singapore these declines are probably caused by increasing use of voluntary sterilization among older women (see **Population Reports**, *Legal Trends and Issues in Voluntary Sterilization*, E-6, March-April 1981).

Several developing countries—including Egypt, Indonesia, and India—have facilities for the production of orals, which are then distributed through the national family planning program. In 1980 this domestic production reached 3.4 million cycles in Egypt, 1.7 million cycles in India, and 11 million cycles in Indonesia—enough to supply over one million women in these countries (382). Most of the raw materials for OCs produced in these countries were supplied by donor agencies.

## Donor Agency Supplies

Another source of information is the records of various national and international donor agencies that purchase contraceptives in bulk and supply them to government and private programs in developing countries. The United States Agency for International Development (USAID), the largest such provider, has delivered almost 100 million cycles per year to developing

**Figure 2. Minimum Percentage of Women Age 15–44 Supplied with Oral Contraceptives through Commercial Channels in 18 Developed Countries, 1964–1981**



Source: Data for 1964–1969 from **Population Reports**, *Oral Contraceptives—50 Million Users*, A-1, April 1974. Data for 1970–81 calculated from Table 1. All based on IMS International/America, Ltd., studies prepared for the Population Information Program, 1973, 1977, 1978, and 1981. (240–242)

**The percentage of women buying pills peaked in 1975 in the developed countries where IMS gathers data. The subsequent drop in pill sales seems to have ended in the late 1970s, and for the last several years the percentage of women buying pills has been roughly constant.**

countries since 1974 (see Table 2; see also **Population Reports**, *OCs—Update on Safety, Effectiveness, and Research*, A-5, January 1979). This represents about three-quarters of all such deliveries annually. These supplies would serve about seven or eight million women each year. Countries receiving the largest quantities of USAID supplies are Indonesia, Bangladesh, the Philippines, Thailand, Mexico, and Morocco, in that order (401). In 1981 most pills supplied by USAID were Noriday 1 + 50, consisting of 1 mg norethisterone and 50 mcg mestranol. A small proportion were Norminest, consisting of 0.5 mg norethisterone and 30 to 35 mcg mestranol (371). Both are manufactured by Syntex (U.S.A.), Inc.

**Table 2. Deliveries of Oral Contraceptives by Donor Agencies, by Region and Year, 1978–1981**
(in thousands of cycles)

| Region & Donor | 1978 | 1979 | 1980 | 1981 | Total |
|---|---|---|---|---|---|
| **AFRICA** | | | | | |
| **USAID bilateral** | 2,069 | 1,088 | 1,050 | 1,000 | 5,207 |
| **FPIA**[a] | 1,013 | 277 | 518 | 269 | 2,077 |
| **IPPF** | 1,158 | 1,322 | 1,297 | 2,096 | 5,873 |
| **UNFPA**[b] | 300 | 2,600 | 1,500 | 1,100 | 5,500 |
| **Pathfinder** | 360 | 247 | 146 | 325 | 1,078 |
| **SIDA** | — | 2,395 | — | 1,350 | 3,745 |
| **Subtotal** | 4,900 | 7,929 | 4,511 | 6,140 | 23,480 |
| **ASIA & PACIFIC** | | | | | |
| **USAID bilateral** | 69,962 | 59,864 | 68,526 | 83,918 | 282,270 |
| **FPIA**[a] | 12,276 | 17,364 | 9,443 | 970 | 40,053 |
| **IPPF** | 2,379 | 1,426 | 2,259 | 1,990 | 8,053 |
| **UNFPA**[b] | 400 | 3,100 | 100 | 900 | 4,500 |
| **Pathfinder** | — | — | 250 | — | 250 |
| **SIDA** | 50 | — | 50 | — | 100 |
| **CIDA** | — | 4,000 | 4,000 | 4,000 | 12,000 |
| **Subtotal** | 85,067 | 85,754 | 84,628 | 91,778 | 347,226 |
| **LATIN AMERICA & CARIBBEAN** | | | | | |
| **USAID bilateral** | 16,725 | 4,152 | 9,534 | 2,611 | 33,022 |
| **FPIA**[a] | 4,944 | 9,976 | 5,513 | 8,641 | 29,074 |
| **IPPF** | 9,995 | 7,202 | 8,453 | 8,114 | 33,764 |
| **UNFPA**[b] | 1,100 | 500 | 900 | 1,100 | 3,600 |
| **Pathfinder** | 364 | 964 | 458 | 1,067 | 2,853 |
| **Subtotal** | 33,128 | 22,794 | 24,858 | 21,533 | 102,313 |
| **MIDDLE EAST & NORTH AFRICA** | | | | | |
| **USAID bilateral** | 5,790 | 2,753 | 4,661 | 6,691 | 19,895 |
| **FPIA**[a] | 1,747 | 645 | 1,176 | 1,093 | 4,661 |
| **IPPF** | 401 | 425 | 568 | 644 | 2,038 |
| **UNFPA**[b] | 5,800 | 1,100 | 500 | 1,800 | 9,200 |
| **Pathfinder** | 1,669 | — | 2 | — | 1,671 |
| **Subtotal** | 15,407 | 4,923 | 6,907 | 10,228 | 37,465 |
| **EUROPE** | | | | | |
| **FPIA**[a] | — | — | — | 1 | 1 |
| **IPPF** | — | — | — | 20 | 20 |
| **UNFPA**[b] | — | 800 | 600 | 600 | 2,000 |
| **Subtotal** | — | 800 | 600 | 621 | 2,021 |
| **AGENCY TOTALS** | | | | | |
| **USAID bilateral** | 94,546 | 67,857 | 83,771 | 94,220 | 340,394 |
| **FPIA**[a] | 19,980 | 28,262 | 16,650 | 10,974 | 75,866 |
| **IPPF** | 13,933 | 10,375 | 12,577 | 12,864 | 49,749 |
| **UNFPA**[b] | 7,600 | 8,100 | 3,600 | 5,500 | 24,800 |
| **Pathfinder** | 2,393 | 1,211 | 856 | 1,391 | 5,851 |
| **SIDA** | 50 | 2,395 | 50 | 1,350 | 3,845 |
| **CIDA** | — | 4,000 | 4,000 | 4,000 | 12,000 |
| **TOTAL** | 138,502 | 122,200 | 121,504 | 130,299 | 512,505 |

Note: USAID bilateral aid is provided directly to national programs. Supplies purchased by USAID also are distributed by FPIA, IPPF, and Pathfinder.

[a] Figures are for fiscal year.

[b] Estimated from expenditure figures at $0.15 (US) per cycle (39)

Sources: US Agency for International Development (USAID) (371, 401)
Family Planning International Assistance (FPIA) (193)
International Planned Parenthood Federation (IPPF) (92)
United Nations Fund for Population Activities (UNFPA) (39)
Pathfinder Fund (150)
Swedish International Development Authority (SIDA) (155)
Canadian International Development Agency (CIDA) (377)

Oral contraceptives also are supplied with USAID assistance through private organizations such as Family Planning International Assistance (FPIA), which distributed an average of 19 million cycles per year during 1978–81 mainly to other private agencies (193), and the Pathfinder Fund, averaging 1.5 million cycles per year, with the largest shipments to Chile, Peru, and Zaire (150). The International Planned Parenthood Federation (IPPF) provides an average of 13 million cycles per year to member family planning associations throughout the world, including about 2 million from USAID (92, 494). (See Table 2.)

Other donor agencies supply some oral contraceptives. In recent years the United Nations Fund for Population Activities (UNFPA) has supplied an estimated four to eight million cycles a year, with the largest quantities going to Egypt, Ecuador, and Tanzania (39). The Swedish International Development Authority (SIDA) has provided about four million cycles since 1978, mainly to Kenya (155). The Canadian International Development Agency (CIDA) supplied approximately four million cycles per year to Thailand during 1979–81 (377). The West German Agency for Technical Cooperation is planning to provide more than one million cycles annually to Bangladesh during 1982–84 (279).

Donors supply almost all the orals used in Asia. Commercial sales in Asian countries covered by IMS remained low between 1977 and 1980, averaging two million cycles annually. By contrast, since 1974 USAID alone has provided about 70 million cycles per year to countries in Asia.

### Survey Data

Information on use of oral contraceptives can also be derived from survey data, primarily from the World Fertility Survey and Contraceptive Prevalence Surveys (see **Population Reports**, *World Fertility Survey—Current Status and Findings*, M-3, July 1979, and *Contraceptive Prevalence Surveys: A New Source of Family Planning Data*, M-5, May-June 1981). These and similar surveys, which are usually limited to married women of reproductive age (MWRA), show that as many as 46 percent in the Netherlands, 37 percent in Belgium, 36 percent in Hungary, and 28 percent in the UK and São Paulo State (Brazil) were using OCs at the time of the survey (see Table 3).

In the developing countries surveyed, prevalence rates among married women of reproductive age range from over 20 percent in Costa Rica, São Paulo State (Brazil), Hong Kong, Jamaica, Mauritius, Singapore, and Thailand, to 2 percent or less in Nepal, Pakistan, Sri Lanka, and Kenya. Generally, oral contraceptive use is highest in Latin America, where most supplies come from commercial sources. In many of the countries surveyed, OCs are the most widely used method. These countries are asterisked in Table 3.

Pill use in the Middle East, where commercial sales are low, has reached substantial levels in several countries, according to survey data. In Jordan in 1976 and in Egypt in 1981, 12 percent of MWRA were using pills. In Africa south of the Sahara there is still almost no pill use and generally very little contraception. While Kenya, Lesotho, and Ghana report 2 percent of MWRA using orals, elsewhere use is probably one percent or less.

### OC Use in China

Estimating OC use in the People's Republic of China has long been difficult because of the lack of data. The government pro-

## Table 3. Percentage of Married Women of Reproductive Age Using Oral Contraceptives (OCs) as Reported by Representative Sample Surveys, 1970–1981

| Region, Country & Year | Ref. No. | % Using | | % of Contraceptors Using OCs[a] |
|---|---|---|---|---|
| | | Any Method | OCs | |
| DEVELOPED COUNTRIES | | | | |
| **Belgium 1971** | 113 | 88 | 18 | 20 |
| **1975–76[b]** | 114 | 87 | 37 | 43 |
| **Bulgaria 1976** | 674 | 76 | 2 | 3 |
| **Canada 1976** | 96 | 62 | 27 | 44* |
| **Czechoslovakia 1970** | 552 | 66[c] | 3 | 4 |
| **1977** | 674 | 95 | 14 | 15 |
| **Denmark 1970[d]** | 552 | 67[c] | 25 | 37* |
| **1975** | 490 | 75[c] | 25 | 33 |
| **Finland 1971** | 552 | 77[c] | 20 | 26 |
| **1976** | 445 | 75[c] | 11 | 15 |
| **France 1972** | 552 | 64[c] | 11 | 17 |
| **1978** | 315 | 79 | 27 | 34* |
| **German Democratic Rep. 1976[e]** | 359 | 63 | 42 | 67* |
| **Hungary 1977** | 235 | 73 | 36 | 49* |
| **Italy 1976–77** | 160 | 77[c] | 22 | 29 |
| **1979** | 674 | 78 | 14 | 18 |
| **Japan 1974** | 555 | 67[c] | 1 | 2 |
| **Netherlands 1975** | 314 | 66 | 46 | 70* |
| **Norway 1977** | 375 | 71[c] | 16 | 23 |
| **Poland 1972** | 552 | 57[c] | 2 | 4 |
| **1977** | 674 | 75[c] | 8 | 10 |
| **Romania 1978** | 555 | 57[c] | 1 | 1 |
| **Spain 1977** | 518 | 50 | 12 | 23 |
| **Sweden 1981** | 700 | 62[c] | 20 | 32* |
| **UK (England & Wales)** | | | | |
| **1970** | 73 | 75 | 19 | 25 |
| **1976** | 151 | 86 | 28 | 33* |
| **US 1970** | 552 | 65 | 22 | 34* |
| **1973** | 170 | 70 | 25 | 36* |
| **1976** | 367 | 68 | 23 | 33* |
| **Yugoslavia 1976** | 674 | 58[c] | 5 | 9 |
| ASIA & PACIFIC | | | | |
| **Bangladesh 1975–76** | 97 | 8 | 3 | 38* |
| **Fiji 1974** | 97 | 41 | 8 | 20 |
| **Hong Kong 1977** | 221 | 72 | 23 | 32* |
| **Indonesia 1976** | 97 | 26 | 15 | 58* |
| **Korea, Rep. of 1974** | 98 | 37 | 9 | 24 |
| **1979** | 366 | 54 | 7 | 13 |
| **Malaysia 1974** | 97 | 33 | 16 | 48* |
| **Nepal 1976** | 97 | 2 | 0 | 17 |
| **Pakistan 1975[f]** | 97 | 5 | 1 | 20 |
| **Philippines 1978** | 97 | 36 | 5 | 14 |
| **Singapore 1973** | 105 | 60 | 22 | 37 |
| **1977** | 105 | 71 | 17 | 24 |
| **Sri Lanka 1975** | 97 | 32 | 2 | 6 |
| **Thailand 1975** | 97 | 36 | 14 | 39* |
| **1978** | 366 | 53 | 22 | 42* |
| AFRICA & MIDDLE EAST | | | | |
| **Egypt 1981** | 131 | 15 | 12 | 77* |
| **Kenya 1977–78** | 556 | 7 | 2 | 30* |
| **Jordan 1976** | 97 | 25 | 12 | 48* |
| **Lesotho 1977** | 674 | 7 | 2 | 24 |
| **Mauritius 1975** | 213 | 46[c] | 21 | 47* |
| **Senegal 1978** | 674 | 4 | 0 | 8 |
| **Sudan (North) 1978** | 674 | 5 | 3 | 67* |
| **Syria 1973** | 483 | 23[c] | 12 | 51* |
| **1978** | 674 | 23 | 14 | 60* |
| **Tunisia (Jendouba) 1979** | 366 | 32 | 7 | 23 |
| **Turkey 1978** | 198 | 50 | 8 | 16 |
| LATIN AMERICA & CARIBBEAN | | | | |
| **Barbados 1971** | 153 | 30 | 8 | 28* |
| **1981** | 131 | 47 | 17 | 36* |
| **Brazil** | | | | |
| **Bahía 1980** | 454 | 31 | 12 | 38* |
| **Paraíba 1980** | 454 | 43 | 14 | 33 |
| **Pernambuco 1980** | 454 | 41 | 13 | 30 |
| **Piauí 1979** | 366 | 31 | 10 | 32 |
| **Rio Grande do Norte 1980** | 454 | 47 | 18 | 38* |
| **São Paulo 1978** | 366 | 64 | 28 | 44* |
| **Colombia 1976** | 98 | 45 | 14 | 31 |
| **1978** | 366 | 48 | 19 | 40 |
| **1981** | 131 | 51 | 19 | 37* |
| **Costa Rica 1976** | 98 | 66 | 25 | 38 |
| **1978** | 366 | 65 | 25 | 38 |
| **1981** | 131 | 66 | 22 | 34* |
| **Dominican Rep. 1975** | 97 | 32 | 8 | 25 |
| **El Salvador 1978** | 366 | 34 | 9 | 26 |
| **Guadeloupe 1976** | 104 | 44 | 10 | 23 |
| **Gautemala 1978** | 366 | 18 | 5 | 28 |
| **Guyana 1975** | 97 | 31 | 9 | 29* |
| **Haiti 1977** | 239 | 25 | 4 | 18 |
| **Honduras 1981** | 131 | 25 | 11 | 44* |
| **Jamaica 1975–76** | 98 | 40 | 13 | 33* |
| **1979** | 366 | 55 | 24 | 44* |
| **Martinique 1976** | 104 | 51 | 17 | 33* |
| **Mexico 1976–77** | 98 | 33 | 12 | 36* |
| **1978** | 366 | 41 | 15 | 37* |
| **Panama 1976** | 98 | 55 | 19 | 35 |
| **1979–80** | 366 | 61 | 19 | 31 |
| **Paraguay 1977** | 366 | 24 | 10 | 42* |
| **1979** | 98 | 39 | 13 | 33* |
| **Peru 1977–78** | 97 | 31 | 4 | 13 |
| **Trinidad & Tobago** | | | | |
| **1970** | 200 | 40 | 15 | 38* |
| **1977** | 547 | 61 | 21 | 35* |
| **Venezuela 1977** | 565 | 60 | 19 | 31* |

Note: Data from Contraceptive Prevalence Surveys (131, 366, 454) exclude douche, abstinence, and "other" from total contraceptive users.

Note: Women surveyed are currently in union (Latin America & Caribbean) or married (elsewhere), age 15–44 or 15–49. Exceptions are: **Developed countries:** Belgium 1971: age 30–34; Belgium 1975–76: age 16–44; Bulgaria: fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; Canada: all women age >14; Czechoslovakia 1970: age <50; Czechoslovakia 1977: fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; Denmark 1970: age 18–49; Denmark 1975: age 18–49; Finland 1971: age 18–54; Finland 1976: in first marriage, age 18–54; France 1972: ever-married, age <45; France 1978: age 20–44; German Democratic Republic: all women, age 15–45; Hungary: age <40; Italy 1976–77: age 18–64; Italy 1979: fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; Netherlands: married continuously since 1963–1973, all ages; Norway: fecund, nonpregnant (excludes users of voluntary sterilization), age 18–44; Poland: age <50; Romania: in first marriage; Spain: fecund, nonpregnant (includes users of voluntary sterilization); Sweden: all women age 20–44; UK 1970: age 16–40; US 1970: ever-married, age <45; Yugoslavia: fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; **Africa & Middle East:** Lesotho: fecund, nonpregnant (includes users of voluntary sterilization); Mauritius: ever-married age <50; Senegal: fecund, nonpregnant (includes users of voluntary sterilization); Sudan: fecund, nonpregnant (includes users of voluntary sterilization); Syria 1978: fecund, nonpregnant (includes users of voluntary sterilization); Turkey: fecund, nonpregnant (includes users of voluntary sterilization); **Latin America & Caribbean:** Barbados 1971: all women, age 15–45; Costa Rica 1976: age 20–44; Haiti: fecund, nonpregnant (includes users of voluntary sterilization); Panama 1976: age 20–44; Trinidad & Tobago 1970: ever in union; Trinidad & Tobago 1977: fecund, nonpregnant (includes users of voluntary sterilization); Venezuela: fecund, nonpregnant (includes users of voluntary sterilization).

*OCs are the most widely used method. (Excludes male and female sterilization in countries where survey excluded sterilization. Otherwise, voluntary sterilization, including male and female, is considered as a single method.)

[a] Due to rounding, figures in this column cannot in all cases be derived from those in preceding two columns.

[b] Flemish only

[c] Excludes sterilization

[d] Excludes central municipalities of Copenhagen

[e] Based on estimates by Mehlan (359)

[f] Questions about use of a specific contraceptive method asked only of those mentioning knowledge of that method in knowledge section of questionnaire.

### Table 4. Oral Contraceptive Use Worldwide, 1980, Estimated Primarily from Sales and Distribution Data

| | Estimated OC Users (in Millions) |
|---|---|
| DEVELOPED AREAS | |
| Commercial sales (IMS, Table 1) | 20 |
| Other commercial sales* | 4 |
| Government programs | 4 |
| **Subtotal** | **28** |
| DEVELOPING AREAS | |
| Commercial sales (IMS, Table 1) | 6 |
| Other commercial sales | 1 |
| Government programs | 12 |
| China | 7 |
| **Subtotal** | **26** |
| **TOTAL** | **54** |

*Countries not covered by IMS audit.

### Table 5. Oral Contraceptive Use Worldwide, 1980, Estimated Primarily from Survey Data

| Region | Estimated % of MWRA Using OCS | Estimated No. of OC Users (in Millions) |
|---|---|---|
| DEVELOPED AREAS | | |
| Australia & New Zealand | 35 | 1.048 |
| Europe | | |
| East (includes USSR) | 5 | 3.560 |
| North (Scandinavia) | 16 | 0.522 |
| South | 12 | 2.568 |
| West | 28 | 9.576 |
| Japan | 0.5 | 0.104 |
| North America | 24 | 10.374 |
| South Africa | 2 | 0.047 |
| **Subtotal** | | **27.799** |
| DEVELOPING AREAS | | |
| Asia | | |
| China | 6 | 7.000 |
| Indian subcontinent | 1 | 1.670 |
| Other Asian | 12 | 7.050 |
| Latin America & Caribbean | 13 | 6.331 |
| Middle East & North Africa | 8 | 3.231 |
| Tropical Africa | 0.5 | 0.288 |
| **Subtotal** | | **25.570** |
| **TOTAL** | | **53.369** |

MWRA = married women of reproductive age

duces and distributes all oral contraceptives in China (108), but exact figures on production or usage have not been available. After visiting a pharmaceutical factory in 1973, Carl Djerassi estimated that 1972 production was sufficient for 20 million users and that actual use would have been at least 15 million (141, 142). More recently, on the basis of discussions with contraceptive production officials in China, Gordon Perkin estimated that total national production in 1979 was sufficient to provide orals for 9 million women. Chinese authorities indicate that there is a gap between production and consumption in the same year. Thus Perkin estimates the number of OC users at between 6.4 and 8 million women (402, 403). As a result of recent emphasis on late marriage and the one-child family (see **Population Reports**, *Population and Birth Planning in the People's Republic of China*, J-25, January-February 1982), sterilization and IUDs, rather than oral contraceptives, are emphasized by birth planning programs.

Estimates of total OC use based on these data suggest that altogether about 53 million women worldwide were using oral contraceptives in 1980, slightly more than half in developed countries (see Tables 4 and 5). Sales and government distribution data are in basic agreement with the available survey data.

## REPRODUCTIVE FUNCTION

As a highly effective method of birth control, oral contraceptives offer women the immediate benefit of preventing unwanted pregnancies. OCs can also be used, like any reliable reversible contraceptive, to space births and minimize the many risks associated with pregnancy and childbirth. In addition, women gain reproductive health benefits from the pill that are not provided by other contraceptives. For example, pill use eases a variety of menstrual disorders, including painful menstruation and premenstrual tension. In OC users the decreased menstrual blood loss associated with OCs may prevent iron-deficiency anemia. OCs provide important protection from ectopic pregnancy and pelvic inflammatory disease. Most recently, it has been suggested that pill use may reduce the likelihood of developing toxic shock. Pill use may also reduce the risk of developing several types of neoplasia that are related to reproductive hormones (see pp. A-202-203).

After OC use, some women experience a delay in becoming pregnant, but there is no evidence that OCs cause permanent sterility or other reproductive problems. Rates of miscarriages and birth defects do not appear to be influenced by previous OC use, although questions remain about birth defects and inadvertent use during early pregnancy. The volume of breast milk and duration of breast-feeding may be reduced by OC use, but no significant reduction in infant weight gain has been seen.

### Effectiveness

The primary purpose and benefit of the pill is to prevent unwanted pregnancies. Among reversible birth control methods, the effectiveness of combined oral contraceptives is second only to that of injectables (208). In theory the pill is over 99 percent effective. Some women do not take the tablets regularly, however, so the actual rate is lower. Studies of married women in the US have found that only 2 to 2.5 percent of women have unplanned pregnancies during their first year of pill use (564, 656). Failure rates have been even lower in the two large British cohort studies of oral contraceptives (472, 575).

In many developing countries failure rates are substantially higher. For example, a 1976 national survey in the Philippines reported 8 pregnancies per 100 woman-years during the first year of pill use, 9.2 during the second year, and 5.1 during the third year (299). In East Java, Indonesia, from 14 to 21 percent became pregnant during the first year of pill use (532). A major problem is irregular pill taking: some women are not accustomed to taking pills on a regular schedule and may not understand that skipping a pill reduces the contraceptive effect (648, 662). According to WHO studies, in some areas as many as 53 percent of users do not take the pills regularly (615).

Poor nutritional status may also reduce effectiveness (51). Comparative studies in five developed countries and 11 developing countries have shown national and individual differences in absorption of ethinyl estradiol (172, 181) and norethisterone (35, 173). Less hormone may be absorbed by malnourished women because their levels of body fat are low (34, 291, 418). Thus they may not be able to use the lowest dose OCs.

### Maternal and Child Health

The pill, like other effective contraceptives, contributes to both maternal and child health by preventing illness and death associated with pregnancy and childbirth. These benefits of OCs are very important in developing countries where maternal mortality is high and maternal and child health problems are common.

In developed countries, maternal mortality appears to be low—between 10 and 30 deaths per 100,000 live births. Nevertheless, several US studies reveal that official figures on maternal mortality may understate the number of deaths actually related to pregnancy by one-quarter to one-half (43, 260, 477, 630). A study in Puerto Rico found that, because of various problems, including the definition of maternal mortality, only 9 of 63 deaths related to pregnancy were officially recorded as pregnancy-related (519, 520). Thus even in developed countries mortality related to pregnancy is not negligible.

In developing countries maternal mortality rates are clearly much higher and probably even more likely to be underrecorded. Reported national rates of about 50 to over 200 per 100,000 births in developing countries average about 10 times higher than in developed countries (see Table 6). Moreover, in rural areas where births generally take place at home maternal mortality is more than 500 per 100,000 live births (66, 107, 133, 207, 266). Lack of adequate health care, combined with the large numbers of older, high-parity women giving birth, accounts for much of these high rates. Illegal abortions are also responsible for many deaths, which contraceptives might prevent (46, 243, 584) (see **Population Reports**, *Complications of Abortion in Developing Countries*, F-7, July 1980).

**Table 6. Maternal Mortality Rates Derived from Vital Statistics, Selected Countries, 1970–1976**
(per 100,000 live births)

| Place | Year | Maternal Deaths[a] |
|---|---|---|
| DEVELOPING AREAS | | |
| **Angola** | 1972 | 108.9 |
| **Egypt** | 1975 | 70.1 |
| **Kenya**[b] | 1970 | 188.1 |
| **Mozambique**[b] | 1970 | 647.4[c] |
| **Chile** | 1976 | 59.3 |
| **Ecuador**[b] | 1975 | 213.0 |
| **Mexico** | 1975 | 106.4 |
| **Philippines**[b] | 1974 | 137.8 |
| DEVELOPED AREAS | | |
| **England & Wales** | 1976 | 12.2 |
| **Yugoslavia** | 1976 | 21.1 |
| **Japan** | 1976 | 25.0 |
| **United States** | 1976 | 11.8 |

[a] Deaths caused by deliveries and complications of pregnancy, childbirth, and the puerperium; excludes deaths caused by abortion except where noted.
[b] Data come from civil registers which are incomplete or of unknown completeness.
[c] Includes maternal deaths associated with induced and spontaneous abortions

Source: United Nations [UN]. Department of International Economic and Social Affairs. Statistical Office. Demographic Yearbook 1978. 30th ed. New York, UN, 1979. (553)

**Table 7. Menstrual Disorders and Oral Contraceptive Use in the Royal College of General Practitioners Oral Contraception Study**

| | Standardized Rate (per 1,000 Woman-Years) | | |
|---|---|---|---|
| | Current Users | Never Users | Relative Risk |
| **Menorrhagia** | 12.48 | 23.62 | 0.52 |
| **Dysmenorrhea** | 3.87 | 10.43 | 0.37 |
| **Irregular menstruation** | 5.19 | 7.92 | 0.65 |
| **Intermenstrual bleeding** | 3.04 | 4.23 | 0.72 |

Note: All differences are statistically significant ($p < 0.01$)

Source: Royal College of General Practitioners. Oral contraceptives and health. An interim report from the oral contraception study of the Royal College of General Practitioners. New York, Pitman, 1974. (472)

Controlling births not only reduces maternal mortality risks but also improves the general health of both women and children. For women, birth control reduces the risk of anemia, malnutrition, and lowered resistance to infectious disease that accompanies the cycle of continuous pregnancy and lactation (257, 478, 479). Children benefit, too, when childbearing is postponed until after age 20 and birth intervals are lengthened (74, 154, 334, 384, 478, 534). In a Kenyan community, for example, mortality between birth and age 5 was 43 percent after birth intervals of less than 1½ years compared with 11 percent after birth intervals of more than 3½ years (228).

### Menstrual Benefits

A high proportion of women taking oral contraceptives experience welcome changes in their menstrual cycles. These include more regular menstrual periods (187, 472) and relief from dysmenorrhea, premenstrual tension, heavy bleeding, and in some cases anemia.

Dysmenorrhea (pelvic pain during menstruation) is widespread. At least half of all women experience some pain, and for 10 percent the pain is severe enough to interfere with daily life (270, 654). OCs relieve menstrual pain so effectively that many doctors have prescribed the pill for just this purpose (129, 270, 364, 654). In a group of US women in the late 1960s, 8 percent took OCs solely to control menstrual disorders (434). The Royal College of General Practitioners Oral Contraception Study in the UK found that reports of dysmenorrhea were 40 percent less frequent among OC users than among nonusers (472) (see Table 7).

OCs can also alleviate another common problem, premenstrual tension. This term encompasses a wide variety of physical symptoms, such as headaches and swelling due to fluid retention, and mental disturbances including anxiety and depression (6, 270). Quantitative definitions of premenstrual tension vary, but most studies show OC users suffer significantly less than nonusers do (364, 398, 509, 635, 672).

Pill use can cut menstrual blood loss by half or more (94, 212, 372) and so may protect against iron-deficiency anemia. Because of iron losses during menstruation, adult women require three times the daily iron intake of men (612). In developing countries iron-deficiency anemia is widespread among women because of inadequate diets, certain parasites, and the extra demands of repeated pregnancies on iron stores. It is estimated

# Studying Oral Contraceptives

Because of the large number of women of reproductive age who take the pill, safety and side effects of OCs have been the subject of continuing research. Two kinds of epidemiological studies—case-control and cohort studies—are most often used to try to detect and measure a link between OC use and a particular condition. Laboratory studies also are necessary to try to discover the physiological mechanisms that cause various conditions.

A typical case-control study, for example, compared the extent of OC use among 175 women hospitalized for venous thromboembolism (the cases) with use among 175 women hospitalized for unrelated reasons (the controls) (485). The fact that 67 of the cases but only 23 of the controls used OCs suggested an association between OC use and venous thromboembolism. The magnitude of difference between the groups is expressed as an estimate of relative risk—in this case, 4.4. Simply put, this means that among these women the OC users were roughly 4.4 times more likely to develop venous thromboembolism than the nonusers (485).

If case-control studies are properly designed, they can identify an association on the basis of a relatively small number of cases even if the condition being studied is rare. All important differences between cases and controls must be known and taken into account, however, and often all relevant differences cannot be identified until a great deal of research has been completed. Most case-control studies can estimate only *relative* risks between two groups, not *absolute* risks.

Cohort studies follow groups of women using and not using OCs over a period of time. They make actual measurements of disease rates in the groups being compared. For example, during the course of one large cohort study 14 current or former OC users died of ischemic heart disease, for a rate of 8 per 100,000 woman-years of OC use. Three never users died of ischemic heart disease, for a rate of 2 per 100,000 woman-years. These findings suggested a relative risk of four associated with OC use (8 ÷ 2) (470, 472). The difference between the two rates is the excess, or attributable risk—in this case, 6 per 100,000 woman-years. These measurements of risk would be applicable only to women with the same characteristics as those in the cohort study. Cohort studies are expensive and difficult to conduct. While they can detect previously unsuspected links between a drug and a disease, they cannot usually provide definitive information on very rare conditions such as pituitary or liver tumors.

There have been three major cohort studies of oral contraceptives, each of them following thousands of OC users and nonusers for many years. All three began in 1968. The two studies in Britain are continuing—the Royal College of General Practitioners Oral Contraception Study and the Oxford University/Family Planning Association (Oxford/FPA) Study. In the US, the Walnut Creek Contraceptive Drug Study, sponsored by the US National Institutes of Health, ended in 1977 (427, 434).

The three major cohort studies have differences and similarities (see Table 8):

- The Royal College study enrolled the most women; the Walnut Creek study, the fewest. Only about 20 percent of the observation period at Walnut Creek involved current OC users compared with about 30 percent in the two British studies. Thus the Walnut Creek study is the least powerful in terms of evaluating current use (568). Loss to follow-up has been highest in the Royal College study (434, 470, 575, 580).
- In the Oxford/FPA and Walnut Creek studies the OC users were younger than the comparison groups. By contrast, the Royal College study picked a never user to match roughly the age of each user, so the mean ages of the two groups are the same (see Table 8).
- The age ranges of women enrolled in the studies are different. The age range of the Oxford/FPA study is the narrowest—25 to 39, while the Walnut Creek study included women up to age 54.
- The Royal College study enrolled women using OCs and women who at enrollment had never used OCs. The Walnut Creek study enrolled current OC users, former users, and never users. In both, the contraceptive practice of those who were not current users is not analyzed. The Oxford/FPA study enrolled only current OC, diaphragm, or IUD users.
- At the time they entered the studies, the British women were more likely to smoke than the Americans, but more Americans smoked heavily. In all three studies OC users smoked more than nonusers (see Table 8). All three studies recorded the smoking habits of participants only when they entered the studies. This may underestimate the effects of smoking, since more women are thought to have quit smoking than to have started (470).
- In all the studies the participants experienced lower death rates than the national average for women of comparable age (436, 470, 471, 580).

The general health of the participants, the age groups studied, and smoking habits are important to keep in mind when considering how reported disease rates would apply to other groups of women. Differences among the groups within a study are taken into account statistically, but this does not take account of differences between the women studied and other populations—for example, in areas where few women smoke. Moreover, various changes that may influence results have occurred as the studies progressed. Participants age, so they no longer represent all OC users. The hormone levels in OCs used by most women have dropped substantially since 1968. Women have changed contraceptive methods, so that the comparison groups have not stayed "pure." Participants have been lost to follow-up. Doctors have stopped prescribing OCs to women at high risk of circulatory system disease.

Most early epidemiologic studies concentrated on determining whether a condition was associated with OC use. Now attention focuses on more specific questions such as:

- How much the risks of OC use differ among specific groups of women—for example, older women, women who smoke, women with a family history of certain diseases, women of different races, or women with different patterns of childbearing.
- Whether any risk or, alternatively, any protective effect persists after OC use stops.
- Whether risks or protective effects increase or decrease with length of OC use.
- Whether risks or protective effects depend on the estrogen or progestin dose in OCs or on the specific hormones used.

### Table 8. Characteristics of the Major Cohort Studies of Oral Contraception

| Study, Place, Dates & Ref. No. | Description of Participants | Age Range | Groups at Entry & No. Studied | Mean Age | % Smoking at Entry | |
|---|---|---|---|---|---|---|
| | | | | | Any Amount | Heavy Smoking* |
| **Royal College, UK, 1968–** (472) | Patients of 1,400 general practitioners | 15+ | OC users: 23,611 | 29 | 48 | 12 |
| | | | Never users: 22,766 | 29 | 42 | 8 |
| **Oxford/FPA, UK, 1968–** (575) | Clients of 17 family planning clinics | 25–39 | OC users: 9,653 | 25–29 | 48 | 17 |
| | | | Diaphragm users: 4,217 | 30–34 | 33 | 7 |
| | | | IUD users: 3,162 | 30–34 | 42 | 12 |
| **Walnut Creek, US, 1968–1977** (434) | Members of prepaid health care plan | 18–54 | OC users: 6,107 | 32 | 36 | 21 |
| | | | Former users: 5,547 | 34 | 36 | 21 |
| | | | Never users: 6,503 | 41 | 33 | 20 |

*Royal College and Walnut Creek studies: 20+ cigarettes per day; Oxford/FPA study: 15+ cigarettes per day.

that in developing countries half of all women age 15 to 49 have subnormal levels of hemoglobin, the blood pigment that carries iron (612).

In 1974 the Royal College study found that both heavy menstrual bleeding and iron-deficiency anemia occurred half as often in OC users, both current and former, as in nonusers—statistically significant differences (472). In a Mexican study, moderately anemic women showed significantly higher hemoglobin and serum iron levels after 12 months using low-dose pills or tricyclics (OCs taken steadily for 63 days) (448). Two other studies have shown smaller improvements in hemoglobin status after OC use (419, 432).

### Return of Fecundity

Recent studies have found that conception rates for former OC users are lower than normal only during the first three months after stopping the pill (201, 318, 400). Thus the average pill user waits an extra three months before conception. But is the fertility of some former pill users permanently impaired? Only the Oxford University/Family Planning Association (Oxford/FPA) study has followed both users and nonusers long enough to look at this issue. It found that, after an initial lag, cumulative delivery rates for former pill users and former diaphragm users were virtually the same by 30 months among parous women and by 42 months among nulliparous women (583).

Studies using amenorrhea as a sign of infecundity are also reassuring. They have found that amenorrhea following pill use is the same as other types of functional secondary amenorrhea (26, 233, 249, 545, 646). The fertility problems of women with post-pill amenorrhea probably begin before they use OCs, since they are more likely than other women to have had scanty or irregular menstrual periods before starting the pill (61).

### Pregnancy and Offspring

Early concerns that the pill might have an adverse effect on later pregnancies have not been verified. Numerous studies have concluded that women who discontinue pill use to have children have no increased risk of miscarriage. Nor are their children more likely to have birth defects or to die in infancy (18, 79, 144, 202, 203, 205, 251, 288, 412, 463, 465, 474, 575, 582, 664).

Of more concern is the effect of pills taken inadvertently during early pregnancy. According to the Walnut Creek researchers, pill use during pregnancy, due to human error or pill failure, is "not rare. . . . If the frequencies observed in this study can be applied to the rest of the population in the U.S., they indicate that over 70,000 fetuses are exposed to OCs annually . . ." (508). Pill use during pregnancy does not appear to affect miscarriage and infant mortality rates (204, 205, 582), but its effect on birth defects is less certain. Most recent studies, several of them large, have found no link between pill use during pregnancy and birth defects in general (204, 487, 582, 664), specific major malformations (204, 487), or heart defects in particular (167, 464). One exception is a report by Dwight Janerich and colleagues. They found that mothers of infants with major structural defects were twice as likely as other mothers to have used OCs in the cycle just before conception or during pregnancy (664). Another study found an association between neural tube defects and OC use during pregnancy or during the three months preceding conception (669).

### Breast-Feeding

The majority of studies show that combined OCs somewhat reduce breast milk volume or shorten the duration of lactation. Weight gain, however, which is the best indicator of the breastfed infant's health, is not significantly affected by the mother's use of combined pills with 50 mcg or less of estrogen (95, 183, 196, 230, 273). Progestin-only pills and injectables do not reduce milk production and in some cases may increase it (40, 101, 184, 194, 544). In many developing countries, however, progestin-only pills and injectables are not available.

Women taking OCs, no matter what type, excrete small quantities of hormones in their breast milk that are consumed by the infant. No serious adverse effects have been observed, but the long-term impact, if any, has not been well studied. Research and recommendations concerning hormonal contraceptives and breast-feeding are reviewed in **Population Reports**, *Breast-Feeding, Fertility, and Family Planning*, J-24, November-December 1981.

### Pelvic Inflammatory Disease

Pelvic inflammatory disease (PID) begins as an acute infection and may lead to chronic infection, pain, and blockage of one or both fallopian tubes. Infertility or ectopic pregnancies often result (597, 598). There are many causes of PID, including sexually transmitted diseases such as gonorrhea and *Chlamydia*, postpartum and postabortion infections, tuberculosis, schistosomiasis, and filariasis (157, 220, 512). Although the incidence of PID varies widely, it is a major and growing health problem in both developed and developing countries (130, 369).

An important benefit of oral contraceptives is that they protect against PID. Pill users have half the risk of PID of most other women (6, 158, 472, 598) and perhaps one-quarter the risk of women who use the IUD, which appears to increase PID (91, 158, 164, 274, 392, 495, 598). This protective effect ceases after women stop taking the pill (6, 472). The most detailed study found that only women who had taken the pill for more than a year were afforded some protection. This group had one-third the risk of all other women in the study (6). It has been estimated that OCs prevent some two to three million cases of PID annually in the developing world (495).

Oral contraceptives may protect against PID in a variety of ways. They may hinder the movement of bacteria from the vagina to the uterus by thickening the cervical mucus barrier and reducing menstrual flow (158, 209, 598). They may limit the spread of infection from the uterine cavity to the fallopian tubes by decreasing the strength of uterine contractions (209). Additionally, progestins may inhibit the growth of gonococcal bacteria in the fallopian tubes (158, 598). Finally, like any contraceptive, the pill prevents pregnancies and abortions, which provide opportunities for infection.

### Ectopic Pregnancy

Because a woman using the pill rarely ovulates, she faces substantially less risk than other women of ectopic pregnancy—that is, implantation and development of the fertilized ovum outside the uterus (usually in the fallopian tubes) (391, 582). Since a history of PID can account for one-third to one-half of all ectopic pregnancies (19, 215, 335, 348, 585, 591, 599), the pill's protective effect against PID also helps to prevent ectopic pregnancies. This protection is important. In the US perhaps 8 in 1,000 pregnancies are ectopic (391). In some developing countries ectopic pregnancy may be even more common (326, 369, 385, 562, 585). An ectopic pregnancy is frequently an emergency that can cause severe pain, internal bleeding, shock, and sometimes death, as well as infecundity in survivors (324).

The Women's Health Study in the US has estimated that current pill users face one-tenth as much risk of ectopic pregnancy as women who use no contraception. They face one-third the risk of current users of IUDs or of condoms, diaphragms, spermicides, or withdrawal (391). In the Oxford/FPA study, no unplanned pregnancies in OC users were ectopic, compared with 6.9 percent of pregnancies among IUD users, and 0.6 percent of pregnancies among women using other methods or none (582). The protective effect of OCs ends once pill use is discontinued (474, 582).

### Vaginal Infections

In the 1960s and early 1970s several studies found that OC use significantly increased the risk of vaginal infection (102, 247, 259, 422, 586), while others found that it did not (140, 149, 301) or that the increase was not statistically significant (134, 185, 365, 525). More recent studies indicate that there is a risk attributable to OC use, but it is small and limited to certain kinds of infections.

In a cohort study in the UK, OC users compared with nonusers had a relative risk of 1.2 for the fungus infection candidiasis (often called yeast infection), but were protected (relative risk 0.7) against the parasitic infection trichomoniasis (284). This study has been the only one to control adequately for number of sexual partners, an important confounding factor because these infections can be sexually transmitted. A British case-control study yielded similar relative risks, 1.9 and 0.5 for candidiasis and trichomoniasis, respectively (82). The Royal College study reported slightly higher risks of vaginal infections for OC users than for nonusers (472), but the Oxford/FPA and Walnut Creek studies found no difference (433, 575). In a West German study of 8,300 gynecological patients, yeast infections were more prevalent among OC users than other women (655).

**While personnel like this Indian auxiliary nurse-midwife are taking health care to more women, childbearing is still dangerous in much of the world. Thus the pill's most important health benefit is spacing births and avoiding unwanted pregnancies.** (UNICEF/Nagarajan)

### Toxic-Shock Syndrome

Toxic-shock syndrome, due to *Staphylococcus* infection of mucous membranes, was recently identified in the US through its association with the use of menstrual tampons. The few studies of toxic-shock syndrome suggests that contraception, and perhaps OCs specifically, may protect against the disease. In the largest of three US case-control studies, 12 percent of cases used the pill compared with 20 percent of controls—not a statistically significant difference (11). Two smaller studies found that contraceptive use overall had a significant protective effect, but each individual method did not (135, 497). A reanalysis of the data from these two studies, however, estimated that OC users were about one-fourth as likely to develop toxic shock as women using no contraception, a statistically significant difference (503).

### Ovarian Cysts

Because the pill suppresses ovulation, it protects against functional ovarian cysts, which develop from the normal, cyclical changes of the ovary (575, 684). OCs also make such cysts regress more quickly (681, 699). Even without OCs, functional ovarian cysts usually disappear spontaneously, but some may rupture and so become life-threatening (681).

## NEOPLASIA

Many types of neoplasia in women—and especially cancers of reproductive or related organs—are affected by hormones. Both endogenous hormones (those produced by the body) and externally administered hormones can influence the incidence and prognosis of cancer (665). Thus, when oral contraceptives were introduced, some scientists warned that OCs, especially the estrogen component, might either initiate or promote cancer (659, 660). Two decades of research are reassuring. They have produced no convincing evidence that OCs increase the incidence of breast cancer. In fact, recent studies suggest that OCs have a protective effect against benign (nonmalignant) breast disease, cancer of the endometrium, and cancer of the ovary. This is probably due to the progestin component of OCs, since estrogen is believed to promote cancer in some circumstances. The relationship between cancer of the cervix and OCs, if any, remains unclear because of the need to take account of other factors, especially sexual behavior. To date the only tumors that have been clearly linked to OC use are nonmalignant liver tumors.

Evaluating the relationship between OC use and cancer is difficult for several reasons:

- Cancers often have long latent periods, with 5 to 30 years intervening between exposure to a carcinogen and detection of the disease.
- Estrogen and progestin components have different effects on potential cancer sites, and these effects may vary further in individuals, on specific organs, and by age.
- Neoplasia in the breast and in reproductive organs is related to sexual and/or reproductive behavior. Thus, with cancer, as with PID, a comparable control group may not be easily found.
- Because breast cancer is relatively common, many subgroups of different ages, family histories, and fertility patterns can be analyzed. When many subgroups are analyzed, some statistically significant relationships may be found that arise only by chance.

Nevertheless, more than 20 years have now elapsed since the first, relatively high-dose combined oral contraceptives were marketed. Given the extensive research on OCs, it is less and less likely that any significant risk of cancer remains undetected. In fact, taking the pill may be one of the few positive steps a woman can take that reduces the risk of certain types of neoplasia.

### Breast Cancer

Any connection between breast cancer and OCs would be especially important. In developed countries breast cancer is the most common neoplasm in women and a leading cause of death. Annual mortality rates for all ages are often above 30 or even 40 per 100,000 women (610). One of every 11 US women will develop breast cancer at some time during her life (21). In the developing world, breast cancer is the second most common cancer in women, after cancer of the cervix in Africa and South America and cancer of the stomach in Asia (115). In developing nations, death rates for all neoplasia and for breast cancer in particular are 50 to 90 percent lower than in developed nations (see Table 9). Nonetheless, even a slight change in the frequency of breast cancer would have a major impact on health and life expectancy.

None of the major studies to date has found any relationship between breast cancer and oral contraceptives, either during or after OC use. One problem in studying breast cancer is that the older a woman is when her first child is born, the more likely she is to develop breast cancer later (330). This is true whether the delay in child-bearing is due to late marriage or contraception. Since OCs are an effective and widely used method to delay first births, this factor, if not taken into account, may produce a spurious association between the pill and breast cancer.

The three published cohort studies have found no significant relationship between pill use and breast cancer. With 133 cases of breast cancer reported, the Royal College study found a significant increase in risk for 30- to 34-year-olds, but not for all women under age 35 or under age 40. Thus the finding was probably a chance association (468). In the Oxford/FPA study, with 72 cases, and the Walnut Creek study, with 131 cases, there were no associations between breast cancer and OC use overall or in any age group (578, 691).

The US Centers for Disease Control (CDC), supported by the National Institutes of Health, have undertaken a large case-control study of all breast cancer cases reported in women 20 to 54 years old from eight population-based cancer registries. Preliminary 6-month results involving more than 680 cases show no increased breast cancer risk. The risk of breast cancer was no higher for OC users as a whole or for various specific subgroups, including women whose first use was more than 15 years ago, who used orals for 11 or more years, who had used orals before

**Table 9. Rates of Death from Selected Neoplasms Among Women Age 25–34, 35–44, and 45–54 in Selected Countries**
(in deaths per 100,000 women per year)

| | Age 25–34 | | | Age 35–44 | | | Age 45–54 | | |
|---|---|---|---|---|---|---|---|---|---|
| Place & Year | Breast Cancer | Cervical Cancer | Cancer of Corpus Uteri[a] | Breast Cancer | Cervical Cancer | Cancer of Corpus Uteri[a] | Breast Cancer | Cervical Cancer | Cancer of Corpus Uteri[a] |
| **DEVELOPING AREAS** | | | | | | | | | |
| **Chile 1976** | 0.8 | 4.1 | 0.8 | 9.0 | 16.5 | 2.7 | 29.8 | 35.9 | 7.5 |
| **Costa Rica 1976** | — | 5.7 | — | 7.6 | 9.8 | 4.4 | 21.9 | 28.2 | 6.3 |
| **Egypt 1974** | 1.1 | 0.1 | 0.5 | 4.0 | 0.2 | 1.8 | 7.7 | 0.8 | 4.1 |
| **Hong Kong 1977** | 1.0 | 1.4 | — | 11.3 | 4.7 | 1.4 | 18.3 | 17.8 | 1.7 |
| **Mauritius 1977** | — | 1.6 | 1.6 | 12.3 | 4.9 | — | 20.1 | 20.1 | 11.5 |
| **Philippines 1975[b]** | 1.5 | 0.4 | 1.3 | 6.9 | 1.5 | 4.6 | 12.3 | 3.6 | 8.7 |
| **Thailand 1977[b]** | 0.2 | 0.1 | 1.1 | 1.3 | 0.7 | 4.7 | 2.6 | 2.1 | 7.4 |
| **DEVELOPED AREAS** | | | | | | | | | |
| **England & Wales 1977** | 4.0 | 2.1 | 0.1 | 22.2 | 6.0 | 0.5 | 64.4 | 13.6 | 4.0 |
| **Japan 1977** | 1.5 | 0.3 | 0.6 | 6.5 | 1.6 | 2.8 | 14.2 | 6.0 | 9.3 |
| **United States 1976** | 3.2 | 1.5 | 0.2 | 17.3 | 4.9 | 1.2 | 51.1 | 9.2 | 3.8 |

— Nil or negligible

[a] Includes malignant neoplasms of endometrium, myometrium, body and fundus of uterus, and epithelium of chorionic villi; also unspecified uterine cancer

[b] Civil registration data considered incomplete and therefore unreliable

Source: World Health Organization [WHO]. World health statistics annual: 1979. Geneva, WHO, 1979. (610)

first full-term pregnancy, or who had a family history of breast cancer. Also, there was no duration-of-use effect (685).

Three other case-control studies, in Britain, Yugoslavia, and the US, also concluded that women taking the pill did not face an increased risk of developing breast cancer (89, 441, 546, 574). Other case-control studies have suggested either *increased* risk related to OC use for various periods of time (308, 309, 396, 409) or *decreased* risk in comparison with incidence rates from national surveys (177) or mammogram findings (186). The methodologies used in these studies, however, leave the results in question.

There is some evidence that breast cancer patients who have taken the pill have smaller, lower grade, less advanced tumors, less axillary lymph-node involvement, and reduced mortality (177, 346, 574), although this was not true in the Royal College study (468). This could be the result of bias in the studies, since women who take OCs may examine their breasts more frequently and thus detect tumors earlier.

Several small case-control studies have tried to identify specific subgroups of women in whom OCs might increase the risk of breast cancer. Studies of women with a family history of breast cancer report conflicting findings (68, 89, 346, 397, 409, 574). Most studies of women who took OCs before their first child was born or who used OCs and were older when their first child was born show no higher risk of breast cancer (89, 346, 395, 397, 409, 546, 557). One US case-control study found that among 35 premenopausal women age 46 to 55 with breast cancer, pill use was associated with a relative risk of eight (265). To date this finding has not been confirmed in larger studies. The large US registry-based study has found no increased risk for subgroups of OC users based on family history or use before pregnancy (685).

### Benign Breast Disease

Oral contraceptives protect users against benign breast disease (BBD). This protective effect, observed in many studies since 1972 (76, 280, 389, 472, 484, 576), has been confirmed by the most recent research. The strongest evidence comes from an analysis of 616 cases and 616 controls from the Oxford/FPA study. For women using OCs, the relative risk of fibroadenoma was 0.4; of chronic cystic disease, 0.7; of unbiopsied breast lumps, 0.6 (88). In a Yugoslavian case-control study involving 497 cases of BBD, the relative risk of cystic disease for OC users was about half that for nonusers. For fibroadenoma and other kinds of BBD, pill use appeared to exert a protective effect, but it was not statistically significant (441). In Italian and Canadian cohort studies, OC users had from 10 to 45 percent less risk of developing BBD than women who had never taken the pill, depending on the length of OC use and the type of BBD (219, 426). Both a Canadian (309) and the Oxford/FPA studies (88) found that the protective effect increased with duration of use.

Protection against benign breast disease seems to depend on the progestin component of the pill, but the mechanism involved remains unknown. In the Oxford/FPA study, women whose pills contained a high, 2.5 or 3.0 mg dose of the progestin norethisterone acetate had about half the relative risk of chronic cystic disease as women using a low, 1.0 mg dose of the same progestin. Estrogen doses were the same (88). As women shift to lower dose pills, protection against benign breast disease may be reduced (309).

Some study results on OCs, BBD, and breast cancer seem contradictory. On one hand, OC use protects against BBD, a disease known to be associated with increased risk of subsequent breast cancer. On the other hand, OC use does not reduce breast cancer risk, as might be expected. Moreover, three studies have found a significantly greater risk of breast cancer for pill users with a history of BBD—a risk that increased with duration of pill use (89, 309, 409). Preliminary results from the US registry study, however, do not confirm this finding in either women who took OCs before or after BBD was diagnosed (685).

One possible explanation is that OC use protects against only that type of BBD which does not later develop into breast cancer (68, 116, 289). A case-control study of the pathology of cystic disease in OC users and other women supports this theory (323).

### Endometrial Cancer

New evidence indicates that combined oral contraceptives reduce the risk of developing cancer of the endometrium (lining of the uterus). Endometrial cancer typically occurs at annual rates of 10 to 25 per 100,000 women of all ages in developed regions and less than 5 per 100,000 in developing areas (333, 589). In the US, endometrial cancer rates have been increasing. The peak incidence is at ages 55 to 65.

The protective effect applies to users of standard formulations of combined oral contraceptives. In five case-control studies of combined orals only, the relative risk of endometrial cancer to ever-users of the pill (231, 275, 481) and to women using the pill for one year or more (592, 693) ranged from 0.5 to 0.2. In other words, women who had *never* taken OCs had two to five times greater risk of developing cancer of the endometrium. In two of these studies protection was greater if the pill was used for a longer period (231, 275) (see Table 10). The protective effect persists for at least five years (275, 693). Preliminary results from a US population-based study showed that protection was greatest for nulliparous women, who otherwise are at higher risk of endometrial cancer than parous women. CDC researchers estimated that in 1979 OC use prevented about 2,000 cases of endometrial cancer in the US (693).

The role of progestin in combined OCs may be crucial. Estrogen promotes growth in the endometrium that may eventually lead to cancer, while progestin opposes this effect (148, 217, 327). Thus, OC formulations with high progestin content may offer the most protection against endometrial cancer (231). Estrogens prescribed for menopausal symptoms, lacking a progestin component, are associated with a higher risk of en-

**Table 10. Endometrial Cancer and Oral Contraceptive Use, Results of a US Case-Control Study**

| Duration of OC Use (in Years) | %Using OCs | | Relative Risk* |
|---|---|---|---|
| | Cases | Controls | |
| **None** | 89 | 80 | 1.0 |
| **<1** | 3 | 3 | 0.8 |
| **1–2** | 4 | 6 | 0.5 |
| **≥3** | 3 | 10 | 0.3 |

*Multivariate risk estimate, controlling for use of noncontraceptive estrogens, parity, ponderal index, menopausal status, age at menopause, ethnic group, diabetes, education, age, and geographic region

Source: D. W. Kaufman et al. Decreased risk of endometrial cancer among oral-contraceptive users. New England Journal of Medicine 303(18): 1045-1047, October 30, 1980. (275)

dometrial cancer (25, 32, 199, 232, 258, 329, 350, 383, 601, 629). Sequential oral contraceptives may have the same effect, since they expose women to estrogens unopposed by progestins for a portion of the cycle. Two recent reports support the suspected association between endometrial cancer and Oracon, an exceptionally estrogenic sequential oral contraceptive that is no longer on the market (71, 592).

### Ovarian Cancer

Oral contraceptives may also protect against ovarian cancer. In most countries of North America and Europe annual incidence is 10 to 20 cases of cancer of the ovary, fallopian tube, and broad ligament per 100,000 women of all ages. Ovarian cancer constitutes the large majority of these cases. Incidence increases with age. Comparable figures for areas in the developing world range from 3 to 7 cases per 100,000 women of all ages (589). Ovarian cancer has a poor prognosis; even with the best treatment, the 5-year survival rate is only 20 percent (566). In the US it accounts for 6 percent of all female cancer deaths (21). The 1977 the US death rate for ovarian cancer was 9.4 per 100,000 women of all ages (558) (see Table 9).

The results of four US case-control studies support earlier findings (370) that OC use provides some protection against later ovarian cancer. In a Los Angeles study a lower risk of developing ovarian cancer was associated with (1) a larger number of live births, (2) a larger number of less than full-term pregnancies, and (3) greater length of OC use. Considered separately, each association lacked statistical significance. When pregnancy and pill use, which both prevent ovulation, were considered together, there was a significant protective effect (100). Similar results were obtained in Washington, D.C., where the control group had more pregnancies and live births and were more likely to have used oral contraceptives than the women with ovarian cancer (352). In another recent study, the protective effect was concentrated in younger women: OC users age 35 or less were one-fifth as likely to develop ovarian cancer as nonusers. The number of cases in young women was small, and the difference was not statistically significant (602).

A recent study by the US Centers for Disease Control, involving 179 cases, found a relative risk of 0.6 for ever-users of OCs. The protection increased with longer use and was strongest for nulliparous women. A protective effect persisted for more than 15 years after first use of OCs. These results suggest that OC use in the US averted about 1,700 cases of ovarian cancer in women age 20–54 in 1979 (137).

According to some recent theories, ovulation produces cysts that trap portions of the epithelium within the ovary. These cysts may be precursors of epithelial ovarian cancer (163, 368, 628). Thus, the suppression of "incessant ovulation," whether by pill use, pregnancy, or full breast-feeding, would reduce the risk of developing ovarian cancer (163).

### Cervical Neoplasia

Cervical neoplasia is the most common cancer among women in South America and Africa (115). Incidence rates vary widely throughout the world, ranging from 5 to 42 cases per 100,000 women of all ages annually (589). Early detection markedly increases a woman's chance of survival (21), so the pattern of death rates differs from that of incidence rates. Death rates of 5 to 6 per 100,000 women age 35 to 44 annually are typical of the US and Britain. Somewhat higher death rates are reported in South America, and lower rates, in Asia (589) (see Table 9).

FAMILY PLANNING CENTRE
RURAL HEALTH CENTRE DACCA

**As well as preventing pregnancy, oral contraceptives reduce the risk of pelvic inflammatory disease, ectopic pregnancy, anemia, and endometrial and ovarian cancer. Here a woman obtains oral contraceptives at a family planning center in rural Bangladesh.** (USAID)

The effect of oral contraceptives on cervical cancer is still in question. Three special problems complicate the evaluation of studies. First, there is a diagnostic bias towards pill users because they are more likely than other women to have Papanicolaou smears (the diagnostic screening procedure that detects cervical neoplasia). Therefore cases in pill users are more likely to be detected. Second, researchers often study the more common dysplasia (or abnormalities) that develops in the cervix, rather than carcinoma in situ (CIS) or invasive cancer. Dysplasia does not necessarily progress to invasive cancer (110). Third, and most important, sexual behavior influences the risk of developing cervical cancer (110). Cervical cancer is linked to number of sexual partners and to age at first coitus (47, 206, 345, 360, 466, 533). It may be caused by a venereally transmitted agent (54, 110, 169, 425, 511) and perhaps initiated by such an agent during adolescence when the cervix is especially vulnerable (123, 321, 510). At least in the US, OC use is associated with greater coital frequency (549, 595) and more sexual partners (533). Therefore sexual behavior, which is difficult to measure accurately, is a confounding factor in the analysis of OCs and cervical cancer. There may be other confounding factors. One study found that smoking affected the risk even when sexual behavior was taken into account (206).

The most important of the many recent studies on OCs and cervical neoplasia are the four that tried to take account of sexual behavior. Three of these four found OC users had 1.3 to 3.4 times the risk of nonusers (206, 360, 533), and the fourth found no higher risk (604). In one of these studies, a British case-control analysis of 237 women with abnormal Pap smears and 422 controls, both the number of sexual partners and pregnancy outside marriage affected the risk of developing cervical dysplasia or carcinoma in situ. OC use contributed significantly to risk, however, even when these variables were controlled for. Women taking the pill for 5 to 9 years had a risk 1.8 times as great as nonusers, while use for 10 years or more posed 2.1 times the risk (206).

A cytological screening program in Quebec (Canada) revealed that age at first coitus was associated with OC use and that both of these factors were independently associated with the incidence of dysplasia. In women younger than 20 at first coitus, 3.7 percent of the OC users had cervical dysplasia compared with 2.7 percent of the nonusers. Among the others, 2.3 percent of OC users and 1.8 percent of nonusers had dysplasia. In both comparisons the differences are statistically significant (360).

Shanna Swan and Willard Brown, reanalyzing the data from the Walnut Creek study on a case-control basis, discovered that the number of sexual partners and the age at which regular intercourse began were the most significant sexual factors in cervical cancer risk. After controlling for sexual behavior, the risk was significantly greater for women who had taken the pill for four to six years, but not for shorter or longer periods. In the 4-to-6 year group, OC users' relative risk ranged from 1.6 to 3.4 depending on the level of sexual activity (533).

### Benign Liver Tumors

Taking the pill greatly increases the risk of developing a nonmalignant liver tumor, but even among users the tumors are extremely rare (576). US hospital discharge records suggest an annual incidence rate of 1.2 benign liver tumors per 100,000 OC users (263). Another indirect calculation estimates 3.4 cases annually per 100,000 US women who have used low-dose OCs for two years or more, compared with about 0.1 per 100,000 in nonusers and short-term users (455).

Benign liver tumors (especially hepatocellular adenomas) in OC users are more likely than those in nonusers to rupture and cause bleeding into the tumor itself and into the peritoneal cavity. Shock and death may result from this massive blood loss unless surgery is performed immediately (24, 50, 111, 278, 285). Bleeding is more likely in pill users probably because the lesions are larger, with a greater incidence of peliosis hepatis (small blood-filled spaces with an endothelial lining) and more vascular changes (285, 373). Lesion size (373) and the risk of preoperative bleeding (455) increase with the duration of OC use in cases of hepatocellular adenoma.

Recent animal experiments have tried to assess the impact of estrogen and progestin components of oral contraceptives on the development of both benign and malignant liver tumors. Three experiments on rats have indicated that estrogens, either alone or in combination with progestins, do not initiate tumors but increase the size of pre-existing ones (286, 536, 623). Another series of experiments on rats suggests that progesterone also may play a role by stimulating abnormal cell proliferation (136).

### Melanoma

Light-skinned populations are at greater risk of melanoma (skin cancer) than dark-skinned populations. Annual incidence rates for women range from 4 to 6 per 100,000 in Europe and North America to less than 2 per 100,000 elsewhere (589).

There is no conclusive evidence that the use of OCs increases the risk of developing melanoma. A 1977 interim report of 22 cases from the Walnut Creek study first raised such suspicions (60). In 1980 a second analysis of the Walnut Creek data reported standardized rates of 28 per 100,000 woman-years for ever users and 8 for never users of OCs, for a statistically significant relative risk of 3.5. The higher incidence among OC users, however, may be due to differences in exposure to the sun, which is known to be associated with melanoma (691). Neither the two British cohort studies (15, 277) nor a recent British case-control study (15) shows a consistent relationship between OCs and melanoma. In a recent US case-control study, the effect of OCs was protective, although significantly so in only some analyses. This study involved more than 200 cases and took account of major confounding factors (156). Further, melanoma incidence and mortality rates in Europe and North America show no increase for women relative to men after the introduction of OCs in the early or middle 1960s (529).

### Pituitary Tumors

Whether oral contraceptives have any relationship to pituitary tumors is unclear. Medical professionals agree that in recent decades the number of pituitary tumors diagnosed has increased (23, 268, 442, 505), but this might be the result of better diagnostic techniques (103, 442, 502). Nevertheless, the condition remains rare and is difficult to study.

Information on OC use and pituitary tumors is scarce. The two British cohort studies had identified only six cases by 1980, too few to detect any possible association between pituitary tumors and the pill (605). A US case-control study, involving 20 cases of prolactin-secreting pituitary tumors, is the largest study. It found that women with tumors were four times as likely as controls to have used OCs—a statistically significant difference (537). The only other case-control study involved nine cases, only four of which were the prolactin-secreting type of tumor that might be associated with OCs. Risk was lower for the OC users in this group, but not significantly so (125).

Most of the information on pituitary tumors is in the form of case series. Pill users account for a substantial proportion of the cases in some pituitary tumor series (37, 103, 255, 268, 505). In most series of amenorrhea or amenorrhea-galactorrhea cases, however, OC use was not more common among women whose amenorrhea was due to pituitary tumors than among women whose amenorrhea had other causes (182, 234, 249, 268, 287, 342, 502, 545, 561).

## CIRCULATORY SYSTEM DISEASE, AGE, AND SMOKING

Latest results from the major cohort studies show more clearly than ever that the increased risk of death from circulatory system disease is concentrated among women over age 35, especially women who smoke. For women under age 35 the risk of death is very small.

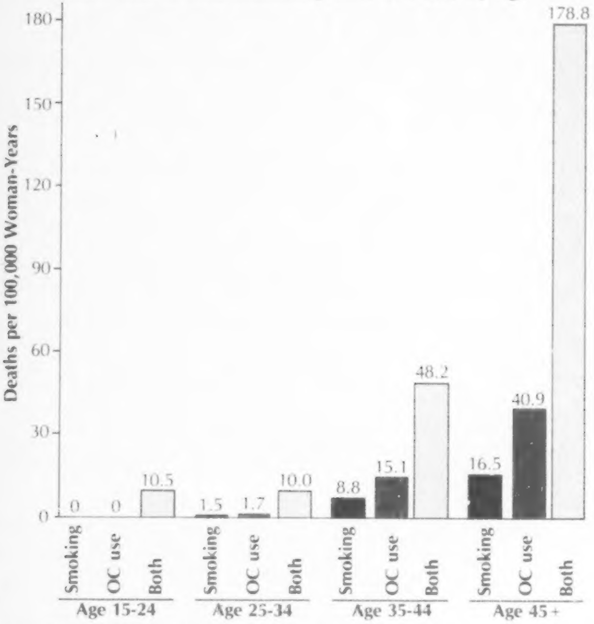
Researchers have found that OCs are associated with a higher risk of four specific circulatory system diseases—venous thromboembolism, ischemic heart disease (including heart attack), cerebrovascular disease (stroke), and hypertension (see pp. A-204-209). Research to date has focused on white women in the US and UK. How these findings apply to other women is not clear, and more research on other groups is needed.

In 1981 both British cohort studies reported lower overall relative risks of death from circulatory system disease than they did in 1977 (470, 471, 579, 580). In the Royal College study the risk relative to never users declined for current users but not for former users. Relative risks based on almost 325,000 woman-years of observation and 65 deaths were 4.0 in current users and 4.3 in former users (470).

The Oxford/FPA study, with fewer women and younger average age, reported 16 circulatory system disease deaths, of which 13 could be analyzed—10 in OC users and 3 in others. The relative risk of 2.5, based on over 140,000 women-years of observation, was not statistically significant (580).

Three factors may help to explain the decline in relative risk seen in the British studies: (1) more observation may have led

**Figure 3. Rates of Excess Circulatory System Disease Mortality in the Royal College of General Practitioners Oral Contraception Study Attributable to Smoking, Ever-Use of Oral Contraceptives, or Both, by Age**



Note: Rates shown are excess over rates in nonsmoking women not using OCs. For absolute rates see Table 11.

Source: Adapted from Royal College of General Practitioners. Further analysis of mortality in oral contraceptive users. Lancet 1(8219): 541-546, March 7, 1981. (470)

to more exact estimates, (2) the lower-dose pills now being used reduce the risk of circulatory disease, and (3) women with a history of circulatory problems or with characteristics identified as risk factors may have shifted to other methods.

The Walnut Creek study reported in 1981 on 22 deaths from new cases of circulatory system disease that occurred in over 127,000 woman-years of observation. The relative risks for ever users were not statistically significant in any age group (436).

### National Mortality Trends

Recently various researchers have tried to see whether an increased risk of death from circulatory system disease among pill users could be detected in national mortality rate trends. Mortality trends have been analyzed by a variety of methods, for specific diseases and circulatory system diseases as a whole, and for countries including the US (447, 541), the UK (236, 607, 678), Sweden (639), Taiwan (109), and a group of 21, largely European, countries (53, 58).

In general, these studies find no change in mortality trends that can be associated with the growth of pill use. Some also find circulatory system disease mortality rates declining faster for women of reproductive age than for men of similar age (109, 541, 607). Only one of these studies, by Valerie Beral, concluded that there was a "clear relationship" between OC use and mortality trends (58). Yet Mark Belsey and colleagues, reanalyzing data for the same 21 countries, could not find such a relationship (53).

The usefulness and interpretation of mortality trend analyses have been controversial (53, 569, 670, 678). Some argue that the results challenge the findings of the cohort and case-control studies linking OCs and circulatory system disease (501, 607). Others argue that the analyses cannot be precise enough to rule out an OC effect (53, 569, 678). Christopher Tietze, after analyzing US data, concluded that mortality trends do not disprove a risk from OCs, but that the fourfold levels of relative risk found by the Royal College study "appear to be exaggerated" when applied to all age groups (542). The findings may not necessarily conflict. The relative risks estimated in cohort and case-control studies may not apply to the great majority of pill users, who are young. For these women, risks are low and deaths are few. Thus no effect of OCs can be seen in the mortality rates for the younger age groups. Instead, the adverse effect is concentrated in older women. Few older women now use pills, however, and so the increased risk is not apparent in mortality trends for these ages, either.

### Age and Smoking

Age and smoking habit are crucial contributors to the risk of OC use. The best evidence comes from the latest report of the Royal College study (see Figure 3 and Table 11):

- For all women under age 35 and for nonsmokers age 35–44, deaths were very few. In these groups, death rates for women who had ever used OCs and for never users were not significantly different.
- When smokers and nonsmokers are compared, OC use posed greater relative and excess risks to the smokers in every age group. (Excess risk is the difference between rates for ever users and never users.)
- When smoking and nonsmoking OC users are considered separately, both relative and excess risk rose with age, but risk rose further among smokers.
- Within each of the older age groups, smoking and OC use interacted to create much higher risk. Thus, risk was lowest for women who neither smoked nor used OCs, somewhat higher and roughly equal for those who either smoked or used OCs, and markedly higher for those who both smoked and used the pill. Put another way, after age 25, OC users who smoked faced about the same risk of death from circulatory system disease as nonsmokers 10 years older who used OCs (470).

**Table 11. Circulatory Disease Mortality Rates and Risks by Age, Smoking Status, and Oral Contraceptive Use, Royal College of General Practitioners Oral Contraception Study, 1981**

| Age & Smoking Status | Deaths per 100,000 Woman-Years (No. of Deaths) | | Relative Risk | Excess Risk per 100,000 Woman-Years |
|---|---|---|---|---|
| | Ever Users | Never Users | | |
| **15–24** | | | | |
| Nonsmokers | 0.0 (0) | 0.0 (0) | — | 0.0 |
| Smokers | 10.5 (1) | 0.0 (0) | — | 10.5 |
| **25–34** | | | | |
| Nonsmokers | 4.4 (2) | 2.7 (1) | 1.6 | 1.7 |
| Smokers | 14.2 (6) | 4.2 (1) | 3.4 | 10.0 |
| **35–44** | | | | |
| Nonsmokers | 21.5 (7) | 6.4 (2) | 3.3 | 15.1 |
| Smokers | 63.4 (18) | 15.2 (3) | **4.2** | **48.2** |
| **45+** | | | | |
| Nonsmokers | 52.4 (4) | 11.4 (1) | **4.6** | **40.9** |
| Smokers | 206.7 (17) | 27.9 (2) | **7.4** | **178.8** |

Statistically significant differences in risk ($p<0.05$) are shown in dark type.

Source: Royal College of General Practitioners. Further analyses of mortality in oral-contraceptive users. Lancet 1(8219): 541-546. March 7, 1981. (470)

## Practical Implications

What are the practical implications of the Royal College findings?

- Women under age 35 can use the pill without adding appreciably to the risk of death from circulatory system disease.
- The safest way to use the pill is not to smoke at the same time.
- For women age 35–45, the Royal College researchers conclude, "these estimates permit a more flexible approach. . . . It is now apparent that the major risk occurs in smokers. Some nonsmokers in this age group who have no other risk factors for vascular disease might find the benefits of oral contraception outweigh the estimated risk . . ." (470).
- For women over age 45, say the Royal College researchers, "we believe that use of oral contraceptives can be justified only in exceptional circumstances" (470).

The Royal College study underestimates the effect of smoking for two reasons: (1) differences in the amount of smoking are not taken into account, and more OC users smoked heavily (see Table 8, p. A-199); (2) smoking status refers to practice at entry into the study, and it is thought that, since then, more women have stopped smoking than have started (470).

In the Oxford/FPA study, 13 of the 16 women (81 percent) who died of circulatory system disease smoked, compared with about 40 percent of all women in the study. Of the 16, 11 both smoked and used the pill. Only two smoked but did not use the pill. Only two used the pill but did not smoke. One neither used the pill nor smoked. All but 3 of the 16 were age 35 or older (579, 580).

In the Walnut Creek study smoking significantly increased the risk of death from circulatory system disease, but pill use did not. A reason for the contrast with the British studies may be little pill use in the oldest women. Thirteen of the 22 deaths involved never users age 50–64—an age group in which only 18 percent were former OC users and 7 percent were current users when they entered the study (434, 436).

The three major cohort studies as well as other cohort investigations and many case-control studies have examined specific circulatory system diseases. Most reinforce the major conclusions of the recent cohort study reports on overall circulatory system disease mortality.

### Venous Thromboembolism

Venous thromboembolism is the blockage of blood flow through the veins caused by blood clots. These clots most often form in the legs but can move to the lungs, causing pulmonary embolism.

In case-control studies the risk of a first episode of venous thromboembolism has ranged from 3 to 11 times higher in OC users than in nonusers (76, 332, 407, 476). The cohort studies have generally found somewhat lower relative risks in their populations. In women without known predisposition to venous thromboembolism, the Royal College study reported a relative risk of over two for superficial clots and just over four for cases of the more serious but rarer deep vein thrombosis (473). The Oxford/FPA study found an overall relative risk of about 3 for all new cases and about 4.5 for new cases requiring hospitalization (575). In the Seattle area of the US, a cohort study of women without any predisposing factors found that the relative risk was over eight, however (688).

What do these relative risks mean in terms of the absolute risk faced by OC users? The answer depends on the women being studied. In the Oxford/FPA study, involving women age 25–39 at entry, the risk of hospitalization for a first episode of venous thromboembolism was 91 per 100,000 woman-years for OC users and 20 for nonusers—a difference of 71 (575). In the Seattle study, involving women age 20–44 without predisposing factors, the relative risk was almost twice as high. The rates of hospitalization for nonfatal episodes, however, were 19 per 100,000 woman-years for OC users and 3 for nonusers—a difference of only 16 (688). Thus, even in apparently similar populations the absolute risks faced by OC users can vary substantially.

The risk of venous thromboembolism associated with pill use is not related to the length of use (76, 192, 224, 237, 473, 485, 572) and disappears after pill use stops (192, 431, 470, 485, 526). Risk is lower with lower estrogen doses (77, 238, 473, 530) (see Table 12).

Unlike some other circulatory system diseases, the risk of thromboembolism does not seem to be greatly affected by age or smoking (305, 332, 473, 572), although case-control analysis of Walnut Creek data did show that smoking increased risk (407). Genetic differences linked with ABO blood type do appear, however. Among white OC users, those women with type O blood have about one-third as much risk of idiopathic deep vein thrombosis as women with other blood types (666).

### Ischemic Heart Disease

When either blood clots (coronary thrombosis) or fat deposits (atherosclerosis) block the arteries of the heart, ischemic heart disease develops. Cutting off the blood supply can cause the

**Table 12. Circulatory System Disease and Use of Oral Contraceptives: Summary of Cohort and Case-Control Studies of White Women in the United Kingdom and the United States**

| Disease | Relative Risk | Risk Affected by: | | | | Other Risk Factors |
|---|---|---|---|---|---|---|
| | | Duration of Use | Dose | | Past Use | |
| | | | Estrogen | Progestin | | |
| **Venous thromboembolic disease** | 2–4 | No | Yes | No? | No | ABO blood type, smoking? |
| **Ischemic heart disease** | 2–6 | Yes? | Yes | Yes? | ? | Age, smoking, hypertension, high cholesterol level, diabetes. |
| **Stroke, thrombotic** | 9 | ? | ? | ? | ? | Hypertension |
| **Stroke, hemorrhagic** | 1.5–4 | Yes? | No? | Yes | Yes? | Smoking, hypertension, race. |
| **Hypertension** | 1–3 | Yes? | ? | Yes | No | Age, race. |

Note: This table summarizes the findings of case-control and cohort studies, with emphasis on the larger studies and more recent reports. For further discussion, see text, pp. A-206-208.

**Table 13. Rates of Death from All Circulatory System Disease and from Selected Diseases Among Women Age 25–34 and 35–44 in Selected Countries**
(in deaths per 100,000 women per year)

| Place & Year | Age 25–34 | | | | Age 35–44 | | | |
|---|---|---|---|---|---|---|---|---|
| | All Circulatory Disease | Cerebrovascular Disease | Ischemic Heart Disease | Venous Thromboembolism | All Circulatory Disease | Cerebrovascular Disease | Ischemic Heart Disease | Venous Thromboembolism |
| **DEVELOPING AREAS** | | | | | | | | |
| **Chile 1976** | 12.3 | 2.6 | 1.4 | 0.3 | 40.0 | 14.3 | 7.9 | 0.9 |
| **Costa Rica 1976** | 13.0 | 0.8 | 1.6 | 1.6 | 37.1 | 5.5 | 5.5 | 8.7 |
| **Egypt 1974** | 51.3 | 1.1 | 1.8 | 0.4 | 75.8 | 3.6 | 5.7 | 1.0 |
| **Hong Kong 1977** | 11.2 | 1.4 | 1.0 | — | 30.2 | 7.5 | 3.3 | — |
| **Mauritius 1977** | 34.4 | 12.5 | 1.6 | — | 56.4 | 14.7 | 12.3 | 2.5 |
| **Philippines 1975*** | 30.2 | 2.5 | 5.4 | 1.1 | 57.6 | 6.5 | 12.8 | 1.4 |
| **Thailand 1977*** | 13.4 | 2.4 | — | — | 33.0 | 5.6 | 0.2 | 0.1 |
| **DEVELOPED AREAS** | | | | | | | | |
| **England & Wales 1977** | 7.0 | 2.7 | 1.4 | 0.5 | 30.2 | 10.4 | 9.7 | 1.5 |
| **Japan 1977** | 7.1 | 2.2 | 0.5 | 0.0 | 25.0 | 12.3 | 2.0 | 0.1 |
| **United States 1976** | 10.5 | 3.3 | 1.9 | 1.2 | 39.0 | 11.6 | 14.6 | 2.2 |

— Nil or negligible
0.0 = Less than 0.05

*Civil registration data considered incomplete and therefore unreliable

Source: World Health Organization [WHO]. World health statistics annual: 1979. Geneva, WHO, 1979. (610)

death of part of the heart muscle—popularly called heart attack and medically termed myocardial infarction. Ischemic heart disease is rare in young women but increases rapidly with age. For example, in the US in 1976 the death rate for women age 25–34 was 1.9 per 100,000. For women age 35–44 it rose to 14.6 per 100,000 (611) (see Table 13).

Case-control studies place the relative risk of heart attack for current OC users at two to four (16, 292, 338, 339, 340, 458, 514, 539). The British cohort studies, analyzing deaths from ischemic heart disease (470) or the broader category of nonrheumatic heart disease (580), report relative risks to current users of about six (see Table 12).

Because the incidence of heart attack rises rapidly with age, pill use poses very little absolute risk to young women, but more to older women. Based on estimated heart attack rates for nonusers in Britain (338, 339, 341), Bruce Stadel estimates that a relative risk of three for women age 30–39 would mean about 7 cases attributable to OCs per 100,000 women annually, but a relative risk of four to women age 40–44 would mean 67 cases per 100,000 (527).

The largest study to date suggests that for older women some additional risk of heart attack may persist for a time after long-term OC use. Specifically, a relative risk of about two appeared for premenopausal women age 40–49 who had used the pill for more than five years during their 30s (514). Among these women, heavy smokers faced the greatest risk (307). The number of women who fit this description is probably quite small (307, 514). This risk to former users might be due to persistent atherosclerotic build-up that was accelerated by pill use (527). On the other hand, some women might have stopped OC use because of circulatory disease symptoms and later had heart attacks.

Smoking is a major cause of heart attack. Overall, women of reproductive age who smoke are two to four times more likely to have heart attacks than nonsmokers (28, 292, 341, 407, 458). For women who smoke heavily, the risk has been estimated at 7 to 34 times as high as for nonsmokers (262, 341, 499). Women who both smoke heavily and use OCs may face even higher risks, as illustrated by a study involving 234 heart attack cases in women of various ages:

**Relative Risk of Heart Attack Associated with Cigarette Smoking and OC Use, Compared with Nonsmoking Nonusers**

| No. of Cigarettes Daily | OC Use | |
|---|---|---|
| | No | Yes |
| None | 1.0 | 4.5 |
| 1–24 | 3.4 | 3.7 |
| 25+ | 7.8 | 39 |

Source: Shapiro, S., et al. Oral-contraceptive use in relation to myocardial infarction. Lancet 1(8119): 743–747. April 7, 1979. (499)

The effect of age compounds the risk. A small US case-control study estimated that the risk of heart attack was 350 to 800 times greater in smoking OC users age 41–45 than in nonsmoking OC users age 27–37 (262).

Both the estrogen and the progestin components of OCs may contribute to the risk of heart attack (238, 357). It has been suspected for some time that risk rose with estrogen dose (238), but higher risk with larger progestin dose is a recent finding. It was first suggested by a comparison of OC sales data for the UK with adverse drug reaction reports to the UK Committee on Safety of Medicines (357). Royal College data now also show a link between progestin dose and the incidence of arterial disease (670).

In addition to older age and smoking, several other factors increase the risk of ischemic heart disease. They include high levels of low-density cholesterol (649, 668), hypertension (667), and diabetes (652, 686). Generally these factors increase risk three- to fourfold. A recent case-control study suggests that in

Britain women with these risk factors or a history of circulatory system disease are no longer taking OCs. Only 2 of 64 women known to have major risk factors were OC users (16).

### Cerebrovascular Disease

Cerebrovascular disease, or stroke, affects blood vessels in the brain. Most strokes, known as thrombotic strokes, are caused by reduced blood flow to the brain after blood clots block the brain's arteries. Ten to 15 percent of strokes, however, are hemorrhagic—that is, caused by bleeding from ruptured arteries. They are more likely to be fatal than thrombotic strokes (588, 679). Bleeding into the space around the brain, called subarachnoid hemorrhage, is the most common type of hemorrhagic stroke in women of reproductive age.

Mortality rates for stroke, like those for heart disease, increase markedly with age. In the US and in England and Wales, the rate is about 3 per 100,000 women age 25-34 annually, about 11 at age 35-44, and about 30 at age 45-54 (610) (see Table 13). Hypertension, more common in older women, substantially increases the risk of both thrombotic and hemorrhagic stroke; smoking increases the risk of hemorrhagic stroke (119, 236, 405, 407, 538).

Thus stroke among OC users is concentrated in older, smoking, and hypertensive women. An interaction of smoking and pill use for hemorrhagic stroke (119, 405) further concentrates the risk. The Seattle cohort study suggests the importance of risk factors. When women with predisposing factors such as hypertension (but not smoking) were excluded, there were no cases of stroke in current OC users and about 7 per 100,000 woman-years in nonusers (688).

For thrombotic stroke, case-control studies report higher but varying risks for OC users than for nonusers (118, 119, 237, 264). The largest study found an overall relative risk of about 9 (118), but risk ranged from 3 for users with normal blood pressure to 14 for users with severe hypertension (119). To date, Walnut Creek is the only cohort study to report many cases of thrombotic stroke. For current or former users, either overall or in any age group, rates were not significantly different from rates for never users (431).

Attention has focused on subarachnoid hemorrhage since 1977, when the Royal College study reported nine deaths, all among current or former users (471). In the most recent Royal College update, with 20 deaths reported, mortality rates were 9 per 100,000 women-years among ever users and 2.3 among never users (470). The Walnut Creek study also reported significantly higher rates for OC users—43 per 100,000 woman-years among current users, 10 among former users, and 4 among never users (431). By contrast, two recent case-control analyses of subarachnoid hemorrhage deaths among English and Welsh women age 15-44 found low relative risks—about 1.5 for nonhypertensive women (236, 539). Also, there has been no noticeable increase in subarachnoid hemorrhage mortality rates for English and Welsh women (236).

The risk of subarachnoid hemorrhage associated with OC use seems to be confined to older women (527). This would help explain the conflict among study results. Of 31 cases in the Royal College and Walnut Creek studies, which found the higher relative risks, only 3 women were under age 35 (405, 470). In the population-based British case-control studies, which found lower relative risks, about half the cases were under age 35 (236, 538). As cohort study participants age, they no longer represent all OC users in the UK or US. Royal College data suggest that a higher risk of stroke persists after pill use stops (470). Walnut Creek data suggest that, for subarachnoid hemorrhage, risk increases with duration of use and persists after pill use stops (405, 407, 431). Risk of stroke may be related to progestin dose (357, 670) (see Table 12).

### Hypertension

Hypertension is higher than normal arterial blood pressure. It is usually defined as a systolic blood pressure reading above 140 mm Hg or a diastolic pressure reading above 90 mm Hg. Hypertension can cause or contribute to death through a variety of complications including heart attack, stroke, heart failure, and renal failure.

OCs raise blood pressure slightly in most white women—about 4 mm Hg systolic and 1 mm Hg diastolic in the Walnut Creek study (168)—although occasionally the increase can be substantial (710). As a result, roughly 1.5 to 3 times as many OC users as nonusers show hypertensive blood pressure readings (168, 189, 438, 472, 593). By contrast, the largest studies of US black women show less increase in blood pressure than among whites (174) or no consistent evidence of increased blood pressure or clinical hypertension (70). Blood pressure is generally higher among US blacks than among whites (558), however, and this might conceal an effect of OCs (70).

Blood pressure increases with age. Thus older OC users are more likely than younger users to be diagnosed as hypertensive (168). Blood pressure also may increase gradually with continued OC use (224, 472) and may be linked to progestin dose (469). For most women blood pressure decreases after OC use stops (168, 593), and diagnoses of hypertension are no more common among former OC users than among never users (438, 472) (see Table 12).

### Mechanisms of Circulatory System Effects

Oral contraceptives may increase the incidence of circulatory system disease in several ways: by affecting the process of

**The risk of circulatory system disease with OC use is concentrated in older women who smoke. For young women, risks are small.**
(Courtesy of American Cancer Society)

blood coagulation, by affecting the levels of various lipids in the blood, and by affecting blood pressure and/or cardiac output. Immunological reactions may also occur in some women (49).

The mechanisms that have received most attention relate to blood coagulation (336). OCs have been shown to induce more rapid platelet aggregation and adhesion (65, 336, 356, 551) and to reduce the activity of the fibrinolytic system, which normally breaks down blood clots (29, 413, 594). Thus, when clots form, they may be less likely to dissolve and more likely to reach a size sufficient to block blood vessels and create a thromboembolic problem. These changes may be greater in women who have naturally low fibrinolytic capacity (30, 411, 526). They have been noted in Asian (551) as well as US and European women, and in adolescents (590) as well as older women. The estrogen component of OCs is thought to be primarily responsible for these changes (120, 238, 357), which appear to reverse when OC use ends.

Some OCs also tend to increase blood pressure, reduce glucose tolerance (394, 427, 522, 621, 643, 691), and reduce levels of high-density lipoprotein (HDL) cholesterol (41, 81, 86, 643). A study of US adolescents suggests that blacks may be less adversely affected than whites (584, 590). These changes, especially in HDL cholesterol, have increasingly been related to progestin levels in OCs. They may play a role in accelerating the process of atherosclerosis—that is, the gradual blockage of blood vessels, especially arteries, by fatty deposits (354, 620).

Bruce Stadel and others have suggested that any impact of OCs on heart attack or stroke risk that persists after use stops may be attributable to these progestin-related effects of OCs (41, 522, 527). Because the risk of death or serious disability is much greater from heart attack or stroke than from venous thromboembolic disorders, some researchers are recommending use of OCs with relatively weak progestins as well as the lowest overall hormone doses (87, 304, 462).

### Application to Developing Countries

Do the findings of epidemiologic and laboratory research, conducted largely with white women in the US and the UK, apply to women in developing countries? On one hand, some of the important risk factors for circulatory system diseases are rare among developing-country women. For example, few women in these countries smoke (117), and their diets are often low in sodium and cholesterol (650, 696). Also, limited research in the US suggests that there may be racial differences in OC effects, with black women less adversely affected than white women (70, 118, 584, 590). Furthermore, the incidence of heart attack and venous thromboembolism are thought to be lower in many developing countries than in developed countries (288, 696, 702, 707), although hypertension and perhaps stroke may be just as common (634, 650, 695, 706).

On the other hand, it has been hypothesized that chronic rheumatic heart disease could put women at special risk from OC use (52, 53). In developing countries chronic rheumatic heart disease may be the most common form of heart disease among young adults (694), and it often goes undetected. The disease leads to increased blood clotting and leaves the heart less able to cope with stress such as increased cardiac output (687, 701, 705). OCs aggravate clotting and may increase cardiac output (310, 587, 675), although not as much as pregnancy does (687, 701). Chagas' disease, a Latin American protozoan infection that causes permanent heart damage, also might make OC users more susceptible to circulatory system diseases (380). This hypothesis about OCs and chronic heart disease has not been tested. Indeed, much more research with developing-country women is needed to determine whether and to what extent OCs affect the risk of circulatory system diseases.

## OTHER CONDITIONS

The intense study of oral contraceptives has generated information on a variety of other conditions, including urinary tract infections, gallbladder disease, rheumatoid arthritis, acne, and nutritional status.

### Urinary Tract Infections

Urinary tract infections, which can cause permanent and serious kidney damage (294, 324), may be slightly more common in women who use OCs than in others, but findings conflict. Also, the inability of these studies to control for sexual behavior casts doubt on the results. The Royal College study found significantly higher rates of clinically proven urinary tract infections for OC users: 1.1 percent of users annually and 0.7 percent of never users had kidney infections; 5.6 and 4.6 percent had bladder infections, and 2.5 and 2.2 percent had other urinary tract infections. Risk rose with estrogen dose (472). Neither the Walnut Creek study nor the Oxford/FPA study found higher rates of urinary tract infection among current pill users, however (433, 567).

Other investigators have studied the incidence of bacteriuria—that is, abnormally high levels of bacteria in the urine. In women without other symptoms, bacteriuria may be a sign of current or potential urinary tract infection (294, 324). Bacteriuria prevalence ranged from 2.4 percent of OC users and 1.6 percent of nonusers in the Walnut Creek cohort (535)—a significant difference—to 13 percent of both users and nonusers in an Indonesian study (399). In six bacteriuria studies (159, 293, 295, 399, 535, 627), all but the Indonesian study found slightly higher rates for OC users, although in most cases the differences were not statistically significant.

### Gallbladder Disease

A link between oral contraceptives and gallbladder disease was first seen in the early 1970s by the Boston Collaborative Drug Surveillance Program, which reported on 212 cases of either gallstones or inflammation of the gallbladder. Pill users were twice as likely as nonusers to develop gallbladder disease, suggesting an annual excess morbidity of 79 cases per 100,000 users (76). Three other case-control studies (222, 226, 486), a study of incidence rate trends for gallbladder disease (313), and the Royal College cohort study (472) have confirmed these findings, although not all the results reached statistical significance. In the Walnut Creek study, however, OC users had slightly lower rates of gallbladder disease than nonusers (437). The Oxford/FPA study recently reported nonsignificant relative risks of 1.3 for current users and 1.2 for ever users. Risk appeared to be concentrated in a few short-term users who may have been prone to gallbladder disease. No increased risk was seen for women using the pill for over a year (631).

### Rheumatoid Arthritis

Two studies suggest that OCs protect against rheumatoid arthritis. In the Royal College study, regardless of dose or duration of use, current pill users were half as likely to develop the disease as nonusers (475). Disease rate trends in a US community support these findings. The annual incidence rate for rheumatoid arthritis rose for both sexes between 1950 and 1965. Since that time rates for men have been stable, while rates for women have dropped sharply. The introduction of OCs in the 1960s could explain this pattern (319). The mechanism of protection may be suppression of the autoimmune response. Pregnancy alleviates rheumatoid arthritis by this mechanism (475).

### Nutrition

Studies in developed countries have found that the pill causes changes in the metabolism of vitamins and minerals, many of which adversely affect biochemical indicators of nutritional status (633, 703). Therefore some nutritionists fear that OC use may provoke nutritional deficiency diseases in poorly nourished women (380, 682, 709). Studies of women with borderline malnutrition in developing countries, however, have shown little or no adverse OC effects on clinical indicators of nutritional status (52, 613, 615, 647), other than alleviating iron deficiency anemia (see p. A-197).

### Acne

Oral contraceptives with different estrogen and progestin levels have different effects on acne (44, 45, 423). This is because estrogens suppress the activity of the sebaceous glands and so help alleviate acne (162, 480, 531, 677), while progestins that are strongly androgenic stimulate the glands to produce even more sebum (312, 608). This variation among pills probably explains why the major cohort studies did not find a strong association—adverse or beneficial—between OC use and acne (437, 472, 575).

### Endemic Diseases

Hormonal contraceptives could, in theory, interact with diseases endemic in developing countries to create or aggravate other conditions. Two case-control studies have suggested that the pill may alter immunological response to malaria, lowering users' resistance to the disease (640, 661). Liver damage caused by parasites might alter hormone metabolism, increase levels of hormone in the blood, and so aggravate OC side effects (380). According to South Korean and Thai studies, however, liver function is not significantly changed in OC users who have liver flukes (112, 615). Schistosomiasis causes greater liver damage than liver flukes and so could be a greater problem for OC users, but it has not yet been studied (637). Sickle-cell anemia increases blood coagulability and stresses the liver, so OC users with sickle-cell disease might be at higher risk of thromboembolic or liver disease (651). The evidence available, however, is limited and inconclusive (632, 657, 676).

## RISKS, BENEFITS, AND PROGRAM ISSUES

Despite two decades of clinical, epidemiological, and survey research, it remains difficult to assess precisely the full array of benefits and risks associated with oral contraceptive use. Because most of this research has involved white women in the US and UK, it is especially difficult to make such assessments for developing countries. Moreover, many important personal factors cannot be quantified. Reliable contraceptives such as OCs prevent the births of unwanted children, who can be both economic and emotional burdens. They also eliminate the constant fear of pregnancy, which may harm marital relations. As Malcolm Potts has pointed out,

> Epidemiologists have not conducted a careful random trial comparing the relative risks of purchasing the pill without a prescription and of having an abortion with a bent coathanger, although these are real choices for many millions of women. The biologist has not found a way of quantitating the cerebral emotions associated with attempting to bring up five children with love and dignity on a dollar a day, compared with the possibility of developing antibodies to sperm ten years after a vasectomy. The committee of medical administrators, who sit in an air-conditioned office of a capital city deciding what tasks should be delegated to medical auxiliaries, cannot know what it means to be in labor for four days, attended by a traditional midwife, to be delivered of a dead baby and left with a rectovaginal fistula. (415)

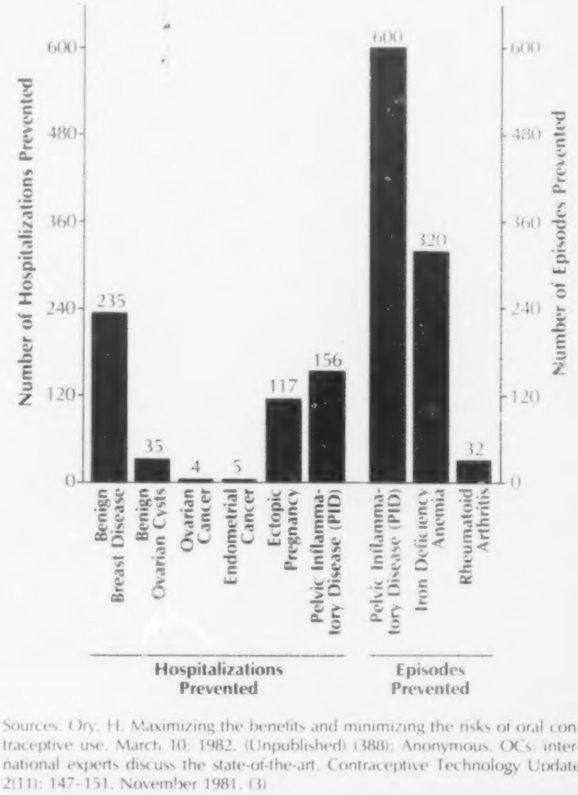
In each setting individuals and community or national family planning programs using OCs need to consider, however imprecisely, such factors as:

- the risks of childbearing,
- risk factors in potential OC users such as age, smoking, and general health status,
- availability of other contraceptive methods, and
- ability of health care services to provide adequate support and back-up.

### Developed Countries

In developed countries maternal mortality is low, and a number of specific risk factors for OC use, such as age, smoking, and hypertension, have been identified. Mortality associated with a year of oral contraceptive use, however, is still lower than the risk associated with pregnancy and childbirth—which is about 20 deaths per 100,000 live births for women under age 35 and about 60 deaths per 100,000 live births for women over 35 (543). In developed countries, even for women who smoke,

**Figure 4. Number of Hospitalizations and Disease Episodes Prevented by Use of Oral Contraceptives in a Group of 100,000 Developed Country Women**



Sources: Ory, H. Maximizing the benefits and minimizing the risks of oral contraceptive use. March 10, 1982. (Unpublished) (388); Anonymous. OCs: international experts discuss the state-of-the-art. Contraceptive Technology Update 2(11): 147–151. November 1981. (3)

the risks of OC use are less than those of pregnancy until after age 35.

A risk-benefit analysis should also take into account noncontraceptive health benefits offered by OCs. For example, Howard Ory estimates that OCs prevent more than 500 hospitalizations per 100,000 US women annually for pelvic inflammatory disease, ectopic pregnancy, cancers of the ovary and endometrium, benign breast disease, and benign ovarian cysts (see Figure 4). Some of these conditions can be life-threatening if medical care is not available. Because of the increasing evidence of significant protective effects of OCs, the Advisory Committee on Fertility and Maternal Health of the US Food and Drug Administration (USFDA) recently recommended that US oral contraceptive labeling discuss these benefits (5). As witnesses from USAID appearing before the Advisory Committee pointed out,

> We cannot expect a woman to make a meaningful personal risk-benefit assessment unless she knows about all of the benefits, as well as the risks, and the relative magnitude of these effects. (456)

Whether USFDA regulations will permit such a change is still unclear (560).

### Developing Countries

Developing countries need risk-benefit analyses appropriate to their own conditions. In developing countries, maternal mortality looms large in assessing the risks and benefits of contraceptive use. As noted, maternal death rates average about 10 times higher in developing than in developed countries (see Table 7, p. A-197).

Some factors put women in developing countries at less risk of OC side effects, while other factors may increase their risk. Smoking is rare (117), but women are generally older when they use contraception (690). Heart attack and venous thromboembolism are thought to be less common in developing countries (548, 696, 702, 707), but hypertension and chronic rheumatic heart disease, which may or may not affect risks of OC use (52), are prevalent in some areas (634, 650, 694). Poor nutrition, parasitic diseases, malaria, sickle-cell disease, and infections that are uncommon in developed areas also might cause special problems for OC users in developing countries. More research on these issues is needed, but so far no reports or research have identified any higher risk for OC users in developing than in developed countries. In general, conditions that might increase the risks of OC use would also be likely to increase the risks of pregnancy even more.

There are several models that compare pregnancy- and contraceptive-related mortality in considerable detail (283, 540, 543, 690, 704). A much simplified model of the risks associated with pregnancy and with the use of reversible methods of contraception is shown in Table 14. The model assumes that among 100,000 fertile women (that is, not sterilized and not experiencing lactational amenorrhea):

- 60 percent of those under age 35 and 40 percent of those 35 and over will become pregnant in one year if they do not use contraceptives (543).
- Maternal mortality (including abortion deaths) in a typical developed country is 20 per 100,000 among younger and 60 per 100,000 among older women (543), while in a developing country it is 100 per 100,000 for women under 35 and 400 per 100,000 for women 35 and over (690).
- Contraceptive failure rates for OCs and condoms are higher in developing countries than in developed countries, especially among younger women (653, 658).

**Table 14. Simplified Model of Annual Mortality Associated with Pregnancy and Reversible Contraception in Developed and Developing Countries**

(per 100,000 fertile women at risk[1])

| Contraceptive Method & User Status | No. of Pregnancies[2] | No. of Maternal Deaths[3] | No. of Method-Related Deaths[4] | Total No. of Deaths[5] |
|---|---|---|---|---|
| **DEVELOPED COUNTRIES** | | | | |
| **None: under 35** | 60,000 | 12 | 0 | 12 |
| **35 & over** | 40,000 | 22 | 0 | 22 |
| **OCs: nonsmoker under 35** | 3,000 | 0.6 | 1 | 2 |
| **smoker under 35** | 3,000 | 0.6 | 10 | 11 |
| **nonsmoker 35 & over** | 2,000 | 1.1 | 15 | 16 |
| **smoker 35 & over** | 2,000 | 1.1 | 48 | 49 |
| **IUDs: under 35** | 5,000 | 1 | 1 | 2 |
| **35 & over** | 3,000 | 1.8 | 2 | 4 |
| **Condoms: under 35** | 14,000 | 2.8 | 0 | 3 |
| **35 & over** | 7,000 | 5.6 | 0 | 6 |
| **DEVELOPING COUNTRIES** | | | | |
| **None: under 35** | 60,000 | 60 | 0 | 60 |
| **35 & over** | 40,000 | 160 | 0 | 160 |
| **OCs: nonsmoker under 35** | 12,000 | 12 | 1 | 13 |
| **smoker under 35** | 12,000 | 12 | 10 | 22 |
| **nonsmoker over 35** | 6,000 | 24 | 15 | 39 |
| **smoker 35 & over** | 6,000 | 24 | 48 | 72 |
| **IUDs: under 35** | 8,000 | 8 | 2 | 10 |
| **35 & over** | 3,000 | 12 | 4 | 16 |
| **Condoms: under 35** | 20,000 | 20 | 0 | 20 |
| **35 & over** | 10,000 | 40 | 0 | 40 |

[1] Women sterilized or in lactational amenorrhea not included

[2] Pregnancy rates in developed countries adapted from Vaughan et al. (564); developing country rates adapted from 18-month rates in Goldman et al. (653)

[3] Maternal death rates in developed countries are estimated at 20/100,000 live births for women under age 35 and 60/100,000 live births for women age 35 and over (543). Maternal death rates in developing countries are estimated at 100/100,000 births for women under age 35 and 400/100,000 for women age 35 and over (690).

[4] Method-related deaths based on Royal College of General Practitioners (470) for OCs and Tietze & Lewit (543) for IUDs and condoms.

[5] No account is taken of deaths prevented by the effects of OCs in reducing anemia, PID, ectopic pregnancy, and cancers of the ovary and endometrium.

- OC-related mortality in developing countries is roughly comparable to OC-related mortality in developed countries, since some risk factors are less common but users are older (658).
- IUD-related mortality in developing countries is roughly double that in developed countries because of increased risk from infections, pelvic inflammatory disease, septic abortion, and possibly ectopic pregnancies that go untreated (283, 690).

Table 14 shows that the situations in developed and developing countries are quite different. In developed countries the greatest reduction in mortality can be achieved by encouraging women age 35 and over either not to smoke or to use other methods of contraception. Among all contraceptors, deaths from pregnancy and childbirth represent a very small part of total mortality. By contrast, in developing countries the great majority of deaths are related to pregnancy, except among OC users age 35 and over who smoke. Among contraceptors, excluding OC users over 35 who smoke, more deaths occur as a result of pregnancies following contraceptive failure than from the hazards of any modern contraceptive method.

# NEW FORMULATIONS AND NEW USES

Research currently underway on combined oral contraceptives includes:

- continuing trials of marketed low-dose OCs (that is, those containing less than 50 mcg estrogen) either alone or in comparison with higher dose pills (42, 69, 78, 127, 178, 250, 358, 467, 616, 618),
- trials of the already-marketed biphasic and triphasic pills, in which the daily hormone doses vary within each cycle (161, 297, 304, 386, 491, 615, 626),
- investigations of the use of a currently marketed OC and of other steroids as one-time postcoital contraceptives, or "morning-after" pills (489, 517, 625, 712),
- comparison of natural estrogens (17 beta-estradiol and estriol) with the commonly used synthetic estrogen ethinyl estradiol as a pill component (31, 75, 496, 617),
- clinical trials of pills containing new progestins (17, 84),
- clinical comparisons of a "paper pill," in which the hormones are carried on a digestible paper base, with a conventional combined OC tablet containing the same hormones at the same dose (48, 444, 616),
- early trials of slowly absorbed "once-a-week" pills (439, 521, 524),
- clinical trials of daily slow-release pills that reduce the total amount of drug required by eliminating peaks in the hormone levels in the blood after pills are taken (176).

Only the first three formulations are commercially available.

### Low-Dose OCs

Low-dose OCs contain less than 50 mcg estrogen. Estrogen content in marketed formulations ranges from 20 to 40 mcg ethinyl estradiol (69, 137, 210, 613, 626). Progestin doses have sometimes also been lowered.

The main advantage of low-dose OCs is a lower risk of circulatory system disease (238, 357, 670) and of minor side effects (9, 618, 712). Low-dose OCs, however, are linked with a greater incidence of two types of menstrual disturbances: breakthrough bleeding and spotting, and skipped menses (9, 62, 250, 467, 713).

For most women, low-dose pills are as effective in preventing pregnancy as standard dose (50 mcg estrogen) pills, with less than one pregnancy per 100 women-years in clinical trials (69, 127, 178, 250, 618). For poorly nourished women, however, low-dose OCs may be less effective, since these women may absorb less hormone than do other women (34, 291, 418).

The effectiveness of OCs also may be reduced when they are taken with any of a number of other drugs. These include: rifampicin (33, 72, 443) and perhaps other antibiotics (34) such as penicillin (508), tetracycline (36), and ampicillin (145, 408); and anticonvulsants (antiepileptics) such as carbamazepin, phenobarbitol, and phenytoin (1, 124, 216, 254, 508). Low-dose OCs may not be appropriate for women who are taking any of these drugs.

### Biphasic and Triphasic Pills

Biphasic and triphasic pills are designed to imitate the hormonal pattern of the menstrual cycle. The daily hormone doses change within the cycle, rather than remaining constant as in conventional combined OCs. This allows lower daily doses in the early portion of the cycle, reducing the total dose per cycle to less than that in most conventional OCs. Slightly higher doses later in the cycle help to prevent breakthrough bleeding and spotting (2, 386, 626). The new formulations appear to be about as effective as standard formulations (2, 296, 386, 491, 626).

A triphasic formulation is marketed by Wyeth International Limited and Schering AG. It consists of 0.05 mg of the progestin levonorgestrel (or dl-norgestrel at twice the dose) and 30 mcg of the estrogen ethinyl estradiol (EE) for days one to 6 of the cycle; 0.075 mg levonorgestrel and 40 mcg EE for days 7 to 11; and 0.125 mg levonorgestrel and 30 mcg EE for days 12 to 22.

A biphasic formulation is marketed by Ortho Pharmaceutical Corporation. It consists of 0.05 mg of the progestin norethindrone and 35 mcg EE for days one to 10 of the cycle and 1.0 mg norethindrone and 35 mcg EE for days 11 to 21.

### Postcoital Use

Certain combined oral contraceptive tablets have been tested as a postcoital contraceptive method to prevent implantation of the fertilized ovum. This method was recommended in 1981 by the International Medical Advisory Panel of the International Planned Parenthood Federation (IPPF) as an appropriate postcoital method for one-time use (245). The World Health Organization is conducting studies on other steroids for postcoital use (616).

Research on postcoital use of OCs has been limited, and only one regimen has been studied recently. The regimen consists of two tablets, each containing 0.5 mg norgestrel (or 0.25 mg levonorgestrel) and 50 mcg ethinyl estradiol (Ovral or Eugynon), taken as soon as possible after coitus, and two more tablets taken 12 hours later but within 72 hours after coitus. In a multicenter study involving treatment of 679 women after single acts of unprotected coitus, 7 pregnancies occurred. Between 30 and 34 pregnancies would have been expected had no contraceptive been used (712).

While the effectiveness of a one-time method is difficult to measure (446, 624), the regimen appears to be as effective as treatment with estrogens alone, which are more commonly used (see **Population Reports,** *Postcoital Contraception: An Appraisal,* J-9, January 1976). It appears to cause less nausea and vomiting than estrogens alone (414, 624)—an important consideration, since these side effects often stop women from taking the full course of estrogens. Also, the combined pills are cheaper and more readily available than estrogens. The treatment takes 12 hours rather than five days (7, 489).

## Program Implications

The implications of these estimates for family planning programs are clear. First, in developing countries greater use of contraceptives will sharply reduce the number of deaths among women of reproductive age. Second, more attention to improving contraceptive effectiveness and preventing unwanted pregnancies also will reduce deaths. Because oral contraceptives can be the most effective reversible method, more attention to assuring proper use of OCs can make a major contribution to reducing both the number of unwanted pregnancies and the number of deaths.

How can family planning programs expand use of oral contraceptives and at the same time make sure that the pills are taken every day on a regular basis? It is increasingly clear that this is not a task that can be assigned just to physicians. In most developing countries, there are too few physicians to provide the personal counseling and time-consuming follow-up often needed to assure daily use. While there is one doctor for every 500 to 800 people in the developed countries, elsewhere the ratio is far smaller. For example, in Chile there is one doctor for every 2,200 people, in Malaysia one for every 4,450, in Bangladesh one for every 11,350, in Nigeria one for every 14,810, and in Tanzania one for every 18,490 (609). The concentration of doctors in urban centers makes the situation even worse in rural areas. In Thailand in 1970 there was one doctor for every 7,000 people overall, but 60 percent of the doctors were located in Bangkok. As a result, the ratio was one doctor per 100,000 people in the rural areas (459). If oral contraceptives were distributed only by physicians or with a doctor's prescription, most women in developing countries would never see OCs or learn how to use them correctly. Whoever normally provides health care to these women is the person who should distribute oral contraceptives (415).

Furthermore, many women may prefer getting contraceptive supplies and advice from other women, from villagers whose views and position are like their own, from pharmacists, or from local health centers staffed by auxiliary health personnel (680, 692). Poor or rural women may be fearful of highly educated physicians, especially men, and either not understand or not want to follow their instructions. The most successful providers of contraceptive information and services may be sympathetic community distributors or other women using the method themselves (298, 461).

Although the lack of doctors in developing countries contributes to many health problems, there is no evidence that it raises the risks associated with OC use. Nonmedical or paramedical personnel are competent to screen women for the most important risk factors: age, smoking, high blood pressure, and any major medical problems (460, 461, 492, 516). Except for such obvious risk factors, doctors cannot easily predict which women will later experience blood clots, heart attacks, or strokes. Pelvic examinations provide little guidance (229). Nonmedical or paramedical personnel can and should tell women about warning signs and symptoms to keep in mind while using oral contraceptives. Developing appropriate instructions and back-up for users should be an important part of any community-based program. The data in Table 14 suggest that in developing countries more lives can be saved by assuring regular daily use of OCs than by establishing elaborate screening procedures to exclude potential users.

**Many women prefer to obtain their contraceptives from sympathetic local women or health auxiliaries rather than from doctors. Nonmedical or paramedical distributors need adequate time for teaching and follow-up to assure that pills are taken regularly.**

Another consideration is the availability and acceptability of other contraceptive methods. As Table 3 shows (see p. A-195), OCs are the most widely used method in many developing countries. An increasing number of women buy them from commercial sources. By comparison, male methods such as condoms are often not acceptable. Voluntary sterilization is appropriate only when one's family is complete. IUDs require training and skill for insertion and, in areas where pelvic inflammatory disease is common, may not be advisable for women who want more children later. Thus oral contraceptives are usually the most readily available and widely acceptable method. While in theory, or in developed countries, barrier methods combined with legal abortion may be the safest way to limit fertility (543), in practice the only choice for many women may be oral contraceptives or nothing.

In conclusion, the latest data from developed-country research suggest that the risks of OC use are confined chiefly to women over 35 who smoke. Moreover, a number of benefits in addition to contraception accrue to women using OCs, including reduced risk of anemia and protection against pelvic inflammatory disease, ectopic pregnancy, and several types of neoplasia. In developing countries, where death rates associated with pregnancy are many times higher than in developed countries, the most important influence on the health benefits and risks of oral contraceptives is use-effectiveness and the problem of assuring regular daily usage. Thus, even though more attention should be given to identifying health problems unique to OC users in different parts of the world, it is unlikely that additional data will fundamentally alter the current risk-benefit calculation. In both family planning and maternal and child health programs, major health gains can be expected from devoting additional time, training, and follow-up to seeing that women who select the pill—or any other family planning method—use it effectively.

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## INTRAUTERINE DEVICES

Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

# IUDs: An Appropriate Contraceptive for Many Women

**Editors' Summary.** About 60 million women worldwide are currently using intrauterine devices (IUDs), including over 40 million in the People's Republic of China. The total number of users has remained relatively stable in recent years. IUD use in most developing countries has not increased as rapidly as the use of oral contraceptives and voluntary sterilization. In Europe, however, where IUDs are readily available from commercial sources, they have become increasingly popular. Despite recent reports of pelvic inflammatory disease (PID) and other infections associated with IUD use in some women, the IUD is an extremely effective, safe, and appropriate method of family planning for many women. It is especially suitable for women who are not exposed to sexually transmitted diseases and who have already borne children.

The life-table event rates per 100 women, by which IUDs are usually evaluated, are approximately as follows after one year of use in large, multicenter studies:

| | |
|---|---|
| Pregnancy | 0.5–5 |
| Expulsion | 5–15 |
| Removal for bleeding/pain | 5–15 |
| Removal for other medical reasons | 3–9 |
| Removal for personal reasons | 1–6 |

Thus, continuation rates one year after insertion tend to range from 50 to 85 percent—high rates for a reversible method.

### Usage Shifts to Copper IUDs

Some shift in usage occurred in the late 1970s from the unmedicated Lippes Loop to copper-releasing IUDs and, to a lesser extent, to IUDs that release progestins into the uterine cavity. Copper devices have now captured much of the market in the United States and Western Europe and amount to about two-thirds of the supplies provided by donor agencies to many developing countries. In China, however, unmedicated devices, usually metal rings or other, locally developed IUDs, are still the rule. Unlike other IUDs, Chinese devices rarely have tails, or strings—a practice that some think may minimize the risk of infection but makes confirmation of the IUD's presence as well as removal more difficult.

Whether the trend toward copper devices reflects fundamental improvements in performance or more aggressive marketing of the copper devices, especially in Europe, is not entirely clear. On one hand, copper devices have some advantages. Compared with the Lippes Loop, some of these devices

- are less likely to be expelled,
- produce less menstrual blood loss,
- are better tolerated by women without children,
- are more likely to stay in place after postpartum or postabortion insertion.

On the other hand, overall continuation and effectiveness rates differ only slightly between copper IUDs and Loops and among the various copper devices. Continuation rates often vary more among different research centers than among different devices. The major disadvantages of copper IUDs are

- possible need for replacement in several years or when the copper is exhausted,
- limited availability, especially of the newer devices,
- cost, which, for government programs, may range from 2 to 20 times the cost of the Lippes Loop, depending on the device, the packaging, and the size of the order.

Paradoxically, several of the copper T devices that have performed well in comparative trials are less widely marketed and used than other copper devices, such as the Cu-7, Nova T, and Multiload, that have not been included in as many comparative studies.

Progestin-releasing IUDs have the advantage of reducing menstrual bleeding well below pre-insertion levels. This could be an important asset where many women are anemic. On the other hand, these devices cost even more than copper IUDs, definitely need replacement after one to two years, produce more midcycle bleeding and spotting, and are associated with a higher rate of ectopic pregnancy.

In general, two decades of IUD research have demonstrated that an improvement in any one facet of IUD performance often adversely affects some other facet. For example, reducing the size of a device to minimize pain or bleeding has raised pregnancy rates.

Recently attention has focused on pelvic inflammatory disease (PID), which is caused by organisms from the lower genital tract that ascend to the uterus and fallopian tubes. PID is frequently

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Phyllis T. Piotrow, Ph.D., Director; Walter Stender, Associate Director; Ward Rinehart, Editor.

due to sexually transmitted diseases or to infection following induced abortion or complications of childbirth. Recent studies in developed countries suggest that PID occurs about 50 percent more often in IUD users than in women using no contraception. It is about two or three times as common in IUD users as in users of oral contraceptives or barrier methods, which provide some protection against PID. The risk is greatest for women who are exposed to sexually transmitted diseases. Thus PID may be of little concern where sexually transmitted diseases are rare as in China but of more concern elsewhere.

Even one or two episodes of PID can cause infertility by permanently blocking the fallopian tubes. Therefore, young women should be fully counseled on the risks of PID and the possible effects of sexually transmitted diseases before choosing an IUD or other contraceptive.

When PID is diagnosed, it should be treated immediately with broad-spectrum antibiotics to minimize tubal damage. Most clinicians recommend removing an IUD if infection does not respond to antibiotics within 24 to 48 hours. There is little reason to remove and reinsert unmedicated IUDs routinely in asymptomatic women, however, since there is no evidence that this would help prevent infection.

If pregnancy occurs with an IUD in place, the dangers of infection and spontaneous abortion are multiplied. Spontaneous abortion occurs about three times more often when an IUD is in place. The risk of septic abortion also is increased. In the US in 1972–74 septic first and second trimester abortions with IUDs in place caused 17 deaths. Physicians were then warned to remove an IUD immediately in case of pregnancy; the Dalkon Shield, which was involved in most of the deaths, was withdrawn from the market. Since these warnings in the mid-1970s, only two septic abortion deaths have been reported among IUD users in the US. Any Dalkon Shield still in place should be removed, since that device may also be associated with higher risk of PID.

Health personnel and IUD users also need to be alert to the possibility of ectopic pregnancy. About one in 30 pregnancies among IUD users is ectopic compared with about one in 125 among nonusers. This is because IUDs provide excellent protection against uterine pregnancies but less against tubal or other extrauterine pregnancies. It is also possible that higher rates of PID or noninfectious tubal changes among IUD users lead to higher rates of ectopic pregnancy after long-term use.

### Issues for the 1980s

During the 1970s attention focused on developing and testing new IUDs to minimize or prevent the problems of pregnancy, expulsion, bleeding, and pain. Improvements have been made, but some of the problems associated with IUDs—such as increased bleeding and infection—remain difficult to prevent.

During the 1980s attention should probably focus less on the search for an ideal device and more on the need for family planning programs to:

- identify suitable candidates for IUDs,
- encourage better health service support for IUD insertion and follow-up,
- make the newer IUDs more widely available to individuals and national programs.

The importance of identifying suitable candidates for IUD use is becoming increasingly clear, since it has not proved possible to develop IUDs that will suit all women. For example, despite a decade of research, no IUD is ideal for nulliparous women or for postpartum insertion. Also, for some women the risk of infection and subsequent infertility may be unacceptably high. Thus, just as the best candidate for oral contraceptives is a young woman who does not smoke or face a high risk of cardiovascular disease, so the best candidate for an IUD may be a woman in a stable marital relationship or an older woman who has already borne children.

For any woman, the quality of health services clearly influences IUD acceptability and safety. Skillful insertion of the IUD at any time in the menstrual cycle that is convenient to the woman, sympathetic counseling on initial problems or side effects, and prompt attention to any suspected infection or pregnancy probably make more difference than the type of device. With careful training, paramedical personnel can insert IUDs as well as physicians can, and they can provide much of the necessary support.

Finally, the newer medicated devices are not now available in most developing countries or in the US, despite considerable clinical experience with some of them. More attention to international distribution mechanisms, possibly more cooperation between public and commercial organizations, and local production of IUDs in some developing countries may be necessary to insure that those who want to use these newer IUDs will be able to obtain and afford them.

If these challenges are met, IUDs can make a substantial contribution to worldwide contraceptive use during the next decade. Compared with the well-documented health risks of an unwanted pregnancy, the risks associated with IUD use are small, and the benefits, substantial.

**End of Editors' Summary.**

## COMPARING IUD PERFORMANCE

While the origins of intrauterine contraception date back to antiquity, IUDs have been widely used only in the last 20 years. The first generation of modern IUDs, the unmedicated, or inert devices such as the Lippes Loop, were designed and first produced in the late 1950s following the development of polyethylene, a biologically inert plastic. Polyethylene can be molded into any configuration and will retain its "memory"—that is, resume its original shape after being bent or straightened. In the 1970s medicated, or bioactive IUDs were developed. These devices carry substances such as copper or hormones. Effort is continuing to design IUDs that will resist expulsion, reduce bleeding, be more appropriate for nulliparous women, and, in the case of medicated devices, remain effective longer.

The IUD is a highly effective method of contraception. In large multicenter clinical trials of different devices pregnancy rates range from 0.5 to about 5 per 100 women per year (see **Population Reports**, *IUDs—Update on Safety, Effectiveness, and Research*, B-3, May 1979). The most recent US survey of contraceptive effectiveness among married women showed a pregnancy rate of 4.8 per 100 IUD users in the first year. By comparison, the pregnancy rate for oral contraceptives was 2.5 per 100 users (151).

In developing countries where women are not accustomed to taking a pill every day, IUDs often have lower pregnancy rates than orals (579, 588). For example, using World Fertility Survey data from five Latin American countries, Noreen Goldman and colleagues estimated that the unplanned pregnancy rate in the 12-month interval after marriage or a previous birth was 5 percent for women who had used an IUD at some time during that period, compared with 8 percent for OC users, 18 percent for condom users, and 40 percent for those using no contraception (577).

In addition to pregnancy rates, other standard measures of IUD performance are rates of expulsion, removal for pain and bleeding, and removal for other medical reasons. In the first year of use roughly 5 to 15 percent of women expel their IUDs, most within the first three months. Prolonged menstrual bleeding and/or pain cause about another 5 to 15 percent to have their IUDs removed within the first year. Pelvic infection and persistent vaginal discharge are the other major medical reasons for discontinuation. In the first year after insertion about 3 to 9 percent of IUDs are removed for these reasons. Removals for personal reasons range from less than one to about 6 percent. Thus overall continuation rates are approximately 50 to 85 percent after 12 months (see **Population Reports**, *IUDs—Update on Safety, Effectiveness, and Research*, B-3, May 1979).

**Over 40 million Chinese women use IUDs—three-quarters of the world's users. Here a gynecologist instructs commune family planning workers about the steel ring IUD. In China these community workers routinely insert IUDs.** (China Reconstructs/Guan Zongzeng)

Most problems occur within the first three months after insertion. After that, occasional complications of IUD use include pelvic inflammatory disease (PID), which may lead to infertility, and septic abortion if the IUD remains in place during pregnancy. Also, the risk of ectopic pregnancy seems to increase with the duration of IUD use, although it is not clear whether IUD users face greater risk than women using no contraception. After more than 20 years of observation, there is no evidence that IUDs initiate or promote cervical, endometrial, or any other type of cancer (191, 511).

In developed countries two decades of research suggest that the IUD is most suitable as a contraceptive method for older women who have had children. IUD effectiveness is greatest and the incidence of complications is lowest among older, parous women. For example, in one clinical trial, among women age 25 and over the pregnancy rate after four years of use of the TCu-380A, a T-shaped IUD with 380 square mm of copper surface, was only 1.0 per 100 users. By contrast, the rate for women age 20 to 24 was 3.2 and for women under 20, 3.7 (439). Also, rates of PID are lower in older women, and rates of expulsion and removal for bleeding and pain decline with parity. In the UK one study found that in women age 30 and over the rate of PID after almost three years of IUD use was only 1.2 per 100 women compared with 6.3 for women age 20 to 24 (49).

### Comparing the Lippes Loop and Copper IUDs

The Lippes Loop, one of the first modern unmedicated devices, is the best known and most widely used device in developing countries other than China. The Loop is available in four types—from the smallest, A, to the largest, D. Since they have been so widely studied, the Lippes Loops C and D serve as the standard for evaluating other IUDs. Copper was first added to IUDs in the 1970s. These IUDs proved to be highly effective even though they are smaller than the Loop.

The IUDs available are roughly equal in contraceptive effectiveness. In comparative studies pregnancy rates for the Loops and early copper devices are within the same range—from 0 to 3.8 per 100 women at one year after interval insertion (see Table 1). In three of four countries where the Population Council organized studies, pregnancy rates for the Loop were slightly lower than for the TCu-200 (434). A multicenter randomized trial of almost 3,000 women, conducted by the World Health Organization (WHO), reports the largest difference between devices. The 18-month pregnancy rates for the Loop and the Cu-7 were similar—3.7 and 3.8, respectively—but lower for the newer TCu-220C—1.7—which has copper on the arms and the stem of a plastic T (551) (see photos, pp. B-118–120).

Although there is considerable variation among research centers, expulsion rates are somewhat lower with the copper T IUDs than with the Loops, while rates of removal for bleeding and pain are virtually the same. Expulsion rates for the TCu-200 were significantly lower than for the Loop in three of four developing countries where the Population Council conducted trials (434) (see Table 1, p. B-104). Pooled data from noncomparative

## Table 1. Performance of Unmedicated and Copper-Bearing IUDs, Selected Comparative Trials, 1972–1980

| Author, Date, & Ref. No. | Place | Devices Studied | No. of Women | Event Rates (per 100 Women) | | | Continuation Rate |
|---|---|---|---|---|---|---|---|
| | | | | Accidental Pregnancy | Expulsion | Bleeding /Pain | |
| **INTERVAL INSERTIONS—12-MONTH RATES** | | | | | | | |
| **Edelman et al.** | Chile | Lippes Loop D | 481 | 3.8[a] | ———17.7[a,b*]——— | | NA |
| **1977** (107) | | TCu-200 | 821 | 2.5[a] | ———11.6[a,b*]——— | | NA |
| | | Cu-7 | 504 | 3.4[a] | ———10.6[a,b*]——— | | NA |
| **Khan et al.** | Bangladesh | Lippes Loop C | 125 | 0 | 11.1[a] | 15.2[a] | 59.5 |
| **1979**[c] (231) | | TCu-220C | 121 | 0 | 6.7[a] | 24.6[a] | 58.4 |
| **Medel et al.** | Chile | Lippes Loop D | 295 | 1.5 | 6.4 | 2.2 | 86.6 |
| **1978**[c] (300) | | TCu-200 | 471 | 2.7 | 6.3 | 1.8 | 82.9 |
| **Sivin 1976** (434) | Colombia | Lippes Loop | 749 | 1.8 | 5.3 | 8.3 | 78.4 |
| | | TCu-200 | 775 | 2.5 | 3.8* | 8.1 | 78.6 |
| | Iran | Lippes Loop | 447 | 1.4 | 7.4 | 11.0 | 78.2 |
| | | TCu-200 | 719 | 2.6 | 9.2 | 12.4 | 71.5 |
| | Korea, Rep. of | Lippes Loop | 951 | 0.4 | 8.6 | 18.2 | 65.5 |
| | | TCu-200 | 1,050 | 1.0 | 6.0* | 19.7 | 68.7 |
| | Thailand | Lippes Loop | 610 | 1.7 | 10.0 | 2.7 | 80.8 |
| | | TCu-200 | 1,996 | 1.0 | 6.7* | 4.3 | 81.9 |
| **Tacla & Baeza** | Chile | Lippes Loop D | 200 | 2.2 | 10.8 | 1.6 | 76.3 |
| **1978**[c] (473) | | TCu-200 | 200 | 2.1 | 8.6 | 3.3 | 73.3 |
| **Tatum 1972**[c] | US | Lippes Loop D | 806 | 2.1 | 10.3 | 7.6 | 73.4 |
| (477) | | TCu-200 | 978 | 1.8 | 5.6 | 4.5 | 83.2 |
| **INTERVAL INSERTION—24-MONTH RATES** | | | | | | | |
| **Medel et al.** | Chile | Lippes Loop D | 295 | 2.3 | 8.1 | 5.0 | 70.6 |
| **1978**[c] (300) | | TCu-200 | 471 | 3.7 | 8.0 | 3.1 | 69.2 |
| **Sivin 1976** (434) | Colombia | Lippes Loop | 749 | 3.1 | 7.4 | 11.2 | 68.6 |
| | | TCu-200 | 775 | 3.8 | 4.3* | 11.6 | 67.5[d] |
| | Iran | Lippes Loop | 447 | 2.7 | 9.1 | 20.4 | 63.3 |
| | | TCu-200 | 719 | 3.6 | 10.2 | 22.5 | 42.8[d] |
| | Korea, Rep. of | Lippes Loop | 951 | 1.0 | 11.7 | 27.0 | 45.5 |
| | | TCu-200 | 1,050 | 1.3 | 8.1* | 28.3 | 50.8[d] |
| | Thailand | Lippes Loop | 610 | 2.5 | 12.2 | 4.1 | 72.6 |
| | | TCu-200 | 1,996 | 1.8 | 8.3* | 6.8 | 69.4[d] |
| **WHO 1980**[c] | Brazil, Egypt, | Lippes Loop D | 2,989[e] | 3.7[a] | NA[f] | 7.9[a] | 54.9 |
| (551) | Hungary, India, | TCu-220C | | 1.7[a] | 6.3 | 3.9[a] | 60.2 |
| | Philippines, | Cu-7 | | 3.8[a] | NA[f] | 6.5[a] | 55.3 |
| | Thailand, USSR, | | | | | | |
| | UK, US | | | | | | |
| **POSTABORTION INSERTIONS—12-MONTH RATES** | | | | | | | |
| **Khan et al.** | Bangladesh | Lippes Loop C | 172 | 4.7 | 10.6 | 16.9 | 57.4 |
| **1979**[c] (231) | | TCu-220C | 172 | 0 | 2.5* | 14.3 | 71.9* |
| **POSTABORTION INSERTIONS—24-MONTH RATES** | | | | | | | |
| **WHO 1980**[c] | Cuba, Hungary, | Lippes Loop D | 2,358[g] | 5.8[a] | NA | NA | 43.2 |
| (551) | India, Rep. | TCu-220C | | 2.2[a]* | | | 50.6 |
| | of Korea, | Cu-7 | | 5.5[a] | | | 43.3 |
| | Singapore, UK, | | | | | | |
| | Yugoslavia, | | | | | | |
| | Zambia | | | | | | |
| | Chile, Egypt, | Lippes Loop D | 1,060[h] | 4.7[a] | NA | NA | ~49 |
| | Philippines, | TCu-220C | | 1.8[a] | | | ~49 |
| | Singapore, | Cu-7 | | 3.3[a] | | | ~49 |
| | UK, Zambia | | | | | | |

NA = not available

*Reported as a statistically significant difference. Some studies do not report tests of significance.

[a] Gross event rates; all other studies report net event rates.

[b] Includes all medical removals

[c] Randomized study

[d] TCu-200 continuation rates exclude women having device removed after 2 years due to uncertainty about its effective lifetime. Net rates for this type of removal: Colombia 1.1%; Iran 12.4%; South Korea 0.3%; Thailand 0.6%.

[e] Multiparous women

[f] Rates for Cu-7 and Lippes Loop D are reported only as higher than for TCu-220C.

[g] Insertions immediately following legal induced abortion

[h] Insertions immediately following illegal induced or spontaneous abortion

4

studies of over 6,700 women in 14 countries, conducted by the International Fertility Research Program (IFRP), also show significantly less expulsion with copper devices than with the Lippes Loop. These pooled data show that rates of removal for bleeding and pain also were lower with the copper devices. Two randomized IFRP studies directly comparing the IUDs, however, found little difference (79). Other studies also report that removals for bleeding and pain occur just as often or more often with some copper devices than with the Loop (231, 434, 473).

The major advantages of copper IUDs over the Lippes Loop are (1) less menstrual blood loss, (2) better tolerance by low-parity women (300, 434), (3) lower expulsion rates after postpartum or postabortion insertion as well as after interval insertion (see p. B-111), and (4) smaller inserter tubes. These advantages may be partly due to the size and shape of the copper devices. They must be weighed against three major drawbacks of copper devices: (1) higher price (see p. B-127), (2) limited availability in many areas, and (3) the recommended requirement for periodic replacement as the copper diminishes. While copper devices are a suitable alternative to the Lippes Loop, they are not necessarily preferable for all women or in all circumstances.

### Comparing Copper IUDs

The first copper IUDs employed copper wire wrapped around the vertical stem of the plastic device (see photos, pp. B-118–120). They are:

**TCu-200**—200 square mm of copper,
**Cu-7**—200 square mm of copper,
**Multiload**—250 or 375 square mm of copper.

The TCu-200, commonly referred to as the copper T, is increasingly used in developing countries. The Multiload is widely used in Western Europe and in Indonesia. Unlike other copper devices, the Multiload comes in four sizes, and one size is available with 375 square mm of copper as well as 250. The Cu-7 is the most widely used copper device in the UK and in the US, where the TCu-200 was approved by the US Food and Drug Administration only in 1979 and where other copper devices are not available. The devices with 200 or 250 square mm of copper have life spans of two to three years, according to manufacturers' recommendations. The Multiload-cu 375 has a recommended life span of three years but is estimated to remain effective for at least five years (578).

Four other T-shaped devices have since been designed for a longer life span and greater contraceptive effectiveness. They are:

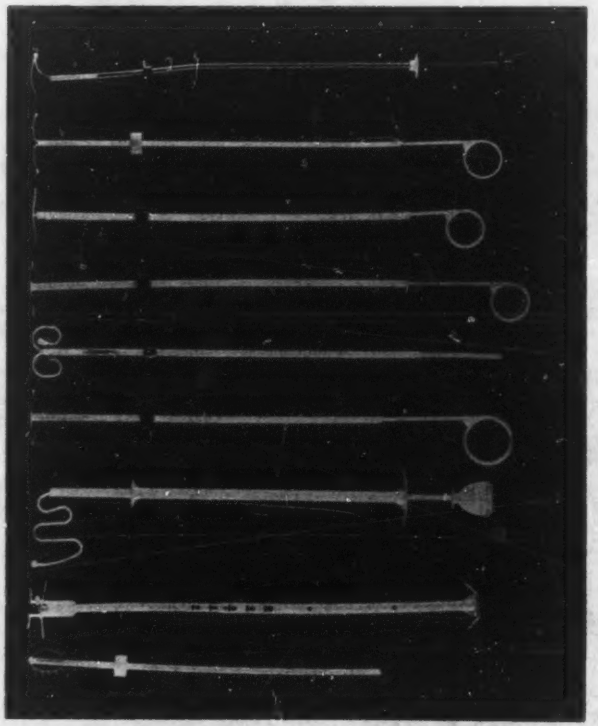
**TCu-380A**—two solid copper sleeves on both the transverse arms and copper wire on the stem, totaling 380 square mm of copper surface,
**TCu-380Ag**—like the TCu-380A, but the copper wire on the stem has a silver core,
**TCu-220C**—seven solid copper sleeves on the stem and arms, totaling 220 square mm of surface,
**Nova T**—200 square mm copper wire with a silver core (see photos, pp. B-118–120).

Copper sleeves were placed on the arms of the TCu-220C and both TCu-380 IUDs to provide a greater surface area of copper in the uterus and to bring the copper closer to the uterine fundus. This placement is thought to improve contraceptive effectiveness, since most implantations of the fertilized ovum occur high in the uterus (438). Unlike copper wire, copper sleeves do not fragment in utero and thus may retain their effectiveness longer. The core of silver in the TCu-380Ag and in the Nova T is intended to reduce fragmentation of the copper wire. The Nova T has an estimated life span of over 10 years; the TCu-380A, of 6 to 10 years; the TCu-380Ag, of 10 to 15 years; and the TCu-220C, of 20 years.

Of these four IUDs, only the Nova T is generally available. It was developed in Finland and is distributed by several European firms. The Nova T is widely used in Western Europe and to a lesser extent in some Eastern European countries, Canada, Latin America, South Africa, and Taiwan (580). The TCu-380A is being manufactured and distributed in Canada by Ortho (317). The TCu-220C is manufactured by Promotora e Importadora PEISA and a modified version, by Biotech Laboratories, both of Mexico (see photos, p. B-119). The modified device is used in the Mexican national family planning program.

Randomized comparative trials with three of the newer devices—the Nova T, the TCu-220C and the TCu-380A—suggest that they prevent pregnancy more effectively than the TCu-200, the standard for comparison in evaluating copper IUDs (see Table 2, p. B-106). In one Population Council comparative study, the 24-month pregnancy rate for the TCu-200 was 5.6 and the rate for the TCu-380A was 1.0. Similarly, in another trial the 24-month pregnancy rate for the TCu-200 was 5.0 and for the TCu-220C, 1.8 (438). Even slightly lower pregnancy rates are an important consideration because pregnancy with an IUD in place constitutes not only a contraceptive failure but also a potential medical complication (see p. B-124).

With these newer copper devices, greater effectiveness and longer life may be offset by increased side effects, however. Removals for bleeding and pain were significantly more common with the TCu-380A than with the TCu-200 (438). Other studies also report lower pregnancy rates but more frequent removal for bleeding and pain with both the TCu-380A and



**IUD inserters and insertion methods vary but are less important to successful insertion than the skill of the operator. Inserters and IUDs are arranged here by overall diameter at insertion, from smallest (top) to largest. Diameter affects discomfort on insertion.**

## Table 2. Performance of Copper-Bearing IUDs, Selected Randomized Comparative Trials, 1975–1981

| Author, Date, & Ref. No. | Place | Devices Studied | No. of Women | Event Rates (per 100 Women) | | | | | Continuation Rate |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Accidental Pregnancy | Expulsion | Bleeding /Pain | Infection | Other Medical | |
| **12-MONTH RATES** | | | | | | | | | |
| **Cooper et al. 1976** (81) | US | TCu-220C | 483 | 0.9 | 3.7 | 14.4 | 0.9 | | 74.9 |
| | | TCu-300 | 516 | 1.1 | 3.1 | 9.3 | 2.1 | | 79.7 |
| **Jain 1975** (214) | US | TCu-200 | 1,839 | 1.5 | 8.8 | 8.4 | 3.4 | | 73.3 |
| | | Cu-7 | 1,831 | 2.8* | 15.5* | 10.0 | 4.0 | | 63.8 |
| **Ladehoff et al. 1981** (243) | Denmark | TCu-200 | 116 | 0.9 | 2.6 | 12.2 | 4.3 | 0 | 73.0 |
| | | Multiload 250 | 124 | 0.8 | 7.5 | 7.4 | 1.6 | 0 | 76.7 |
| **Luukkainen et al. 1979** (287) | Denmark, Finland, Sweden | Nova T | 741 | 0.7 | 4.2 | 10.5 | 1.8 | 1.5 | 77.8 |
| | | TCu-200 | 780 | 1.8 | 4.6 | 11.0 | 2.2 | 1.7 | 75.8 |
| **Prema et al. 1979**† (372) | India | TCu-200 | 250 | 0.9 | 4.6 | 4.3 | NA | 0 | 77.1 |
| | | TCu-220 | 227 | 0 | 4.1 | 5.5 | NA | 0 | 71.5 |
| | | TCu-380A | 281 | 0 | 7.1 | 10.6 | NA | 0 | 63.7 |
| | | Soonawala Y | 119 | 0 | 4.1 | 7.8 | NA | 12.2 | 66.1 |
| **Roy et al. 1979** (399) | US | TCu-220C | 903 | 1.1[a] | 5.7[a] | 15.6[a] | 1.6[a] | | 72.6 |
| | | TCu-300 | 498 | 1.5[a] | 4.9[a] | 10.2[a]* | 2.7[a] | | 76.4 |
| | | TCu-380A | 391 | 0.5[a] | 5.2[a] | 16.3[a] | 3.5[a] | | 72.1 |
| **Sivin & Stern 1979** (438) | US, Canada | TCu-200 | 1,014 | 2.1 | 7.1 | 10.3 | 3.6 | | 72.5 |
| | | TCu-220C | 1,097 | 0.9 | 8.0 | 11.5 | 2.3 | | 73.5 |
| | | TCu-200 | 1,851 | 3.1 | 7.1 | 11.5 | 2.8 | | 70.8 |
| | | TCu-380A | 1,679 | 1.0* | 7.1 | 14.2 | 3.0 | | 69.7 |
| **Tatum 1975** (476) | US, Canada | TCu-200 | 2,479 | 2.9 | 9.4 | 12.0 | 2.8 | | 68.9 |
| | | TCu-300 | 2,394 | 2.6 | 9.6 | 10.1 | 3.9 | | 68.8 |
| | | TCu-200 | 2,772 | 3.2 | 5.9 | 10.7 | 2.5 | | 73.2 |
| | | TCu-380A | 2,199 | 1.1* | 5.7 | 11.8 | 2.8 | | 74.1 |
| | | TCu-200 | 2,196 | 1.5 | 6.1 | 8.0 | 2.3 | | 77.0 |
| | | TCu-220C | 2,198 | 0.6 | 6.7 | 8.9 | 2.1 | | 77.9 |
| **Thiery et al. 1980** (492) | Belgium | TCu-200 | 730 | 1.0[a] | 2.7[a] | 1.4[a] | 0.2[a] | NA | 93.1 |
| | | Multiload 250 | 664 | 0.5[a] | 1.2[a] | 2.3[a] | 0.1[a] | NA | 94.4 |
| **24-MONTH RATES** | | | | | | | | | |
| **Allonen et al. 1980** (15) | Denmark, Finland, Sweden | Nova T[a] | 744 | 1.4 | 5.7 | 16.0 | 2.6 | 2.4 | 64.7 |
| | | TCu-200[a] | 786 | 3.8* | 5.0 | 13.7 | 2.5 | 2.4 | 65.5 |
| **Jain 1975** (214) | US | TCu-200 | 1,839 | 3.8 | 10.0 | 12.6 | 5.9 | | 58.5 |
| | | Cu-7 | 1,831 | 4.5 | 19.5* | 14.3 | 6.1 | | 46.3 |
| **Lefebvre et al. 1979** (261) | Canada | TCu-200 | 537[b] | 2.2 | 6.1 | 15.1 | 0.9 | 2.9 | 62.1 |
| | | TCu-300 | 495[b] | 3.9 | 5.7 | 17.0 | 0.7 | 2.9 | 59.1 |
| | | TCu-200 | 449[c] | 5.1 | 5.3 | 16.6 | 1.0 | 3.1 | 53.0 |
| | | TCu-300 | 462[c] | 2.7 | 3.7 | 13.3 | 0.8 | 2.3 | 58.3 |
| **Lim et al. 1982** (273) | Singapore | Multiload 250[d] | 274[d] | 1.8[a] | 2.9[a] | 8.5[a] | 7.2[a] | | NA |
| | | Multiload 375 | 275[d] | 2.1[a] | 1.8[a] | 12.2[a] | 7.2[a] | | NA |
| **McCarthy et al. 1982** (295) | Singapore | Cu-7 | 299 | 4.3[a] | 15.6[a] | 12.4[a] | 7.6[a] | | 61.9 |
| | | Multiload 250 | 192 | 4.2[a] | 3.7[a]* | 10.7[a] | 10.1[a] | | 71.4 |
| **McCarthy et al. 1982** (296) | Singapore | Cu-7 | 200 | 9.8[a]* | 16.9[a]* | 13.3[a] | 5.4[a] | | NA |
| | | TCu-220C | 200 | 0.6[a]* | 8.5[a]* | 14.4[a] | 4.7[a] | | NA |
| | | Multiload 250 | 200 | 4.0[a] | 2.3[a] | 12.6[a] | 6.7[a] | | NA |
| **Roy et al. 1979** (399) | US | TCu-220C | 903 | 2.6[a] | 8.1[a] | 27.6[a] | 4.4[a] | | 51.8 |
| | | TCu-300 | 498 | 2.6[a] | 8.9[a] | 19.7[a]* | 5.9[a] | | 57.5 |
| | | TCu-380A | 391 | 1.0[a] | 8.7[a] | 27.1[a] | 9.6[a]* | | 50.0 |
| **Sivin & Stern 1979** (438) | US, Canada | TCu-200 | 1,014 | 5.0 | 9.0 | 16.1 | 5.0 | | 55.9 |
| | | TCu-220C | 1,097 | 1.8* | 9.8 | 17.1 | 4.0 | | 59.7 |
| | | TCu-200 | 1,851 | 5.6 | 8.3 | 18.9 | 4.3 | | 50.0 |
| | | TCu-380A | 1,679 | 1.0* | 9.5 | 23.7* | 4.7 | | 50.1 |
| **Thiery et al. 1980** (492) | Belgium | TCu-200 | 730 | 1.2[a] | 3.1[a] | 1.9[a] | 0.2[a] | NA | 90.0 |
| | | Multiload 250 | 664 | 1.1[a] | 1.2[a] | 3.8[a] | 0.1[a] | NA | 89.5 |
| **36-MONTH RATES** | | | | | | | | | |
| **Nygren et al. 1981** (336) | Denmark, Finland, Sweden | Nova T | 746 | 2.0 | 7.0 | 19.9 | 2.5 | 1.7 | 48.8 |
| | | TCu-200 | 783 | 4.8* | 5.2 | 17.9 | 3.1 | 2.6 | 50.9 |
| **Roy et al. 1979** (399) | US | TCu-220C | 903 | 3.4[a] | 10.0[a] | 32.3[a] | 6.4[a] | | 43.0 |
| | | TCu-300 | 498 | 4.3[a] | 11.5[a] | 28.5[a] | 7.8[a] | | 41.1 |
| | | TCu-380A | 391 | 1.0[a] | 13.2[a] | 29.7[a] | 13.3[a]* | | 37.8 |
| **48-MONTH RATES** | | | | | | | | | |
| **Nielsen et al. 1982** (322) | Denmark, Finland, Sweden | Nova T | 746 | 2.2 | 7.6* | 22.9 | 3.4 | 2.1 | 43.2 |
| | | TCu-200 | 783 | 5.0* | 6.4 | 21.5 | 3.7 | 4.5 | 42.4 |

NA = not available

*Reported as statistically significant difference. Some studies do not report significance.

†Not randomized

[a] Gross rates; all other studies report net rates.

[b] Nulliparous women

[c] Multiparous women

[d] Postabortion insertions; all other studies involve interval insertions.

TCu-220C than with the TCu-200 (372, 399, 476). One researcher suggests that this may occur because the copper sleeves reduce the flexibility of these devices (399). Despite differences in some event rates, however, continuation rates are similar for all copper devices.

Studies in several countries with the Multiload-cu 250 and 375 show pregnancy rates of less than 1.0 at one year (243, 280, 446, 515, 518, 519, 520, 547). In randomized comparative trials, however, the pregnancy rates for the Multiload-cu 250 were similar to the rates for the TCu-200 and the Cu-7 (243, 295, 492) and higher than the pregnancy rates for the TCu-220C (296). Preliminary results of a trial comparing the Multiload-cu 375 with the TCu-380Ag show similar and low event rates for both devices (78). One of the first copper devices, the Cu-7, often has been preferred for nulliparous women because the diameter of the inserter tube is small (see photo, p. B-118). Randomized comparative trials with other devices have found that the Cu-7 has higher pregnancy and expulsion rates than the TCu-200, the TCu-220C, or the Multiload 250 (214, 295, 296, 551) (see Table 2). A drawback of the Cu-7 is that the threads can become looped over the upper arm of the device during insertion. Later, if the threads descend, the woman may think that the IUD is being expelled (187).

The Population Council considers its second generation copper devices—TCu-220C, TCu-380A, and TCu-380Ag—superior to the TCu-200 and plans no further developmental research on new copper devices (317). All three of the new copper devices, however, may be more difficult to manufacture and distribute than the Lippes Loop and TCu-200. None of the newer Ts has yet been approved by the United States Food and Drug Administration (USFDA). Therefore, they cannot be supplied by the United States Agency for International Development (USAID), which has been the major provider of IUDs to developing-country family planning programs. Because of differences between the USFDA and the manufacturer over the design of the stem of the TCu-220C, the Population Council has not applied for USFDA approval for this device. USFDA approval of the TCu-380A is expected shortly. Approval for the TCu-380Ag may be requested in 1983 (317). More manufacture in developing countries for local use may eventually be possible (see p. B-126).

Neither the Multiload-cu 375 nor the Nova T has been evaluated to the same extent as the other T devices or the Lippes Loop. Data from international randomized comparative trials of the Multiload conducted by WHO and other agencies have not yet been published. Also, neither device has been used in the US. European reports to date and the increased usage in Europe suggest, however, that the performance of these devices may be comparable to that of the other new copper devices.

## Life Span of Copper Devices

A major disadvantage of copper devices with 200 or 250 square mm of copper wire without a silver core—the TCu-200, Cu-7, and Multiload-cu 250—is the current recommendation by regulatory agencies that they be replaced every two to three years. This adds to the programmatic and personal costs of IUDs and also may expose the woman to the risks associated with reinsertion. Recently, several researchers have challenged this recommendation (157, 445). More than 10 studies have shown that these devices effectively prevent pregnancy for at least four years (107, 139, 199, 238, 247, 322, 438, 491, 551, 568, 569, 570, 578). No studies show any increases in pregnancy rates with duration of use. In some studies rates declined significantly after the first and second years (438, 570).

**A family planning worker in Pakistan describes the IUD and other contraceptive methods. The IUD is a good choice for older, parous women because pregnancy, expulsion, and infection rates are low.** (UNICEF/Wolf)

Perhaps these devices continue to be effective because enough copper remains to prevent pregnancy. In studies in China, Chile, and Sweden, between 50 and 70 percent of the copper on the TCu-200 and Cu-7 devices remained intact after four to five years of use (248, 568, 570). After 60 days, copper in utero dissolves steadily at an estimated rate of about 45 mcg per day (172). At this rate, a device with 200 square mm of copper would have a life span of six years (146). Another study found that the rate of dissolution very slowly decreases over time and after two years of use averages 25 mcg of copper per day (308). Individual variation in the rate of dissolution is wide and may depend on the composition and quantity of uterine secretions (237, 498) and the quality of the copper (237).

Deposits of calcium salt and other organic materials form on some IUDs after less than one year of use (148, 149, 217, 394, 429). Some researchers argue that these deposits can block the release of copper and so impair contraceptive effectiveness (147, 319). Available evidence does not support this view (158, 436), since pregnancy rates do not increase with duration of use (148, 149). And, according to some studies, after an initial decline, the release rate of copper remains fairly constant over time (236, 245, 248, 467, 498). Concern has been expressed about the fragmentation of copper wire in utero (498). The fragments are microscopic in size, and to date there have been no reports of harmful effects (146).

## Steroid-Releasing IUDs

IUDs that release a steroid such as progesterone or levonorgestrel are now in use or being tested. Delivered locally in the uterus, the effective doses of steroid are substantially lower than doses required for oral administration, and systemic side effects are less frequent (356, 419). The steroid-releasing devices appear to perform about as well as the first copper IUDs. The Progestasert, a T-shaped device containing 38 mg of progesterone with a daily release rate of 65 mcg, is the only steroid-releasing device currently marketed. In three recent compara-

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tive trials, pregnancy and continuation rates for the Progestasert were similar to those of the Nova T, the TCu-200, and the Cu-7 (131, 244, 362).

The main advantage of the Progestasert is that it significantly reduces the volume of menstrual blood loss and so increases serum iron levels. Thus it may be a good choice for women who experience heavy bleeding. The Progestasert increases the number of days of bleeding and spotting, however. As a result, it is removed for bleeding just as often, or more often, than other devices. The Progestasert may also relieve dysmenorrhea (see pp. B-116–117).

The recommendation for replacement every 12 months limits the value of the Progestasert for many family planning programs. A new device, containing 52 mg of progesterone and also releasing an average of 65 mcg per day, was tested in a multicenter WHO trial. The trial was stopped after pregnancy rates began to increase at 20 to 22 months (396).

Both WHO and the Population Council are testing other T-shaped devices that release the progestin levonorgestrel. The WHO device, which contains 10 mg of levonorgestrel, has a release rate of 2 mcg daily and an estimated life span of 10 years (551, 552). The release rate was set very low to avoid any possibility of systemic effects. No data on the performance of this IUD are yet available.

The Population Council initially developed two devices—the first containing 43 mg of levonorgestrel released at a rate of 20 mcg daily; the second containing 56 mg released at a rate of 30 mcg daily. A comparative trial of these two devices and the Nova T reported 2-year pregnancy rates of 0.6 with the lower-dose levonorgestrel device, 0 with the other, and 3.3 with the Nova T (284, 329). The greater effectiveness of the levonorgestrel devices may be offset by more side effects. About 20 percent using either of the levonorgestrel devices had them removed for amenorrhea or other hormonal side effects. Cumulative rates of removal for bleeding and pain were similar for all three devices (284, 329). The continuation rate for the Nova T was higher than the rates for the levonorgestrel devices—65.2 per 100 women compared with 56.2 and 52.1 at two years (284). A modified levonorgestrel device with 60 mg of levonorgestrel, releasing 20 mcg daily, is now being tested by The Population Council (437) (see photo, p. B-120).

Research is now underway to find other steroids suitable for intrauterine release. IUDs with the natural estrogen estriol prevent pregnancy in animals (29, 97, 98). Clinical trials in women have just begun (96). In the Netherlands, Willem van Os is developing a Multiload device that releases the progestin desogestrel (517). Devices with the progestin dehydroretroprogesterone were ineffective. Five pregnancies occurred in the first 500 woman-months of use (420). WHO stopped research on a norethisterone-releasing IUD because high doses were required to reduce menstrual blood loss (552).

Despite new designs and the use of different bioactive agents, none of the newer devices has proved to be markedly superior to all others in overall performance and continuation rates. Furthermore, the design changes that improve one aspect of performance often diminish another aspect (228). Moreover, variations in the populations under study, insertion procedures, skill and training of the providers, and methods of counseling and following up users all can affect performance as much or more than the characteristics of a particular device. Differences among studies or among study centers testing the same device are often greater than differences among devices in one study (586). In seven studies of the TCu-200, for example, the 12-month pregnancy rates ranged from 0.9 to 3.2, and the continuation rates, from 69 to 93 per 100 women (see Table 2, p. B-106). Also, pregnancy rates as low as those reported in small clinical trials often are not attained when an IUD is used in national programs. As Lynda Cole and David Edelman conclude:

> Further studies and research are required to evaluate the relative merits of different types of IUDs for use in different populations. Factors other than event rates influence the best IUD choice for a given subject and a given program. It is doubtful that any one type of IUD is best for all women. (79)

## DISTRIBUTION AND USE

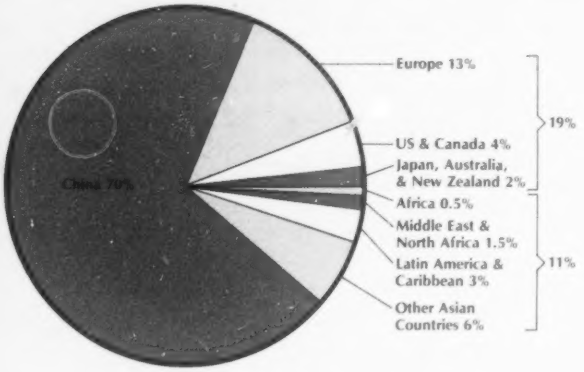
Data from the World Fertility Survey (WFS), Contraceptive Prevalence Surveys (CPS), and other surveys of fertility suggest that the number of women using IUDs has remained fairly stable at about 60 million in recent years (see Table 3). More than two-thirds of all IUD users are in the People's Republic of China (see Figure 1), where about 35 percent of married women of reproductive age use IUDs (72). By contrast, in most developing countries 5 percent or fewer of the women surveyed used IUDs. Only in South Korea and Venezuela do surveys show as many as 10 percent of married women using IUDs (65, 521). In some developing countries the percentage of women using IUDs has stayed roughly constant while the percentage using the pill and sterilization has increased; thus a

**Table 3. Estimated Number of IUD Users Worldwide, 1981**

| Region | Estimated % of MWRA Using IUDs | Estimated No. of IUD users (in 1,000s) |
|---|---|---|
| **ASIA** | | |
| **China** | 35 | 42,300 |
| **Indian subcontinent** | 1 | 1,600 |
| **Other Asia** | 3 | 2,000 |
| **All region** | 13 | 45,900 |
| **AFRICA** | | |
| **Tropical Africa** | 0.5 | 300 |
| **LATIN AMERICA & CARIBBEAN** | | |
| **Brazil** | 0.5 | 80 |
| **All other** | 3 | 1,000 |
| **All region** | 2.2 | 1,800 |
| **MIDDLE EAST & NORTH AFRICA** | | |
| **All region** | 2 | 800 |
| **DEVELOPED COUNTRIES** | | |
| **Scandinavia** | 25 | 600 |
| **Other Europe** | 7 | 7,300 |
| **US & Canada** | 6 | 2,600 |
| **Japan** | 5 | 1,000 |
| **Australia & New Zealand** | 7 | 200 |
| **All region** | 6 | 11,700 |
| **TOTALS** | | |
| **Developing countries, excluding China** | 2 | 6,500 |
| **Developed countries** | 6 | 11,700 |
| **World, excluding China** | 3 | 18,200 |
| **China** | 35 | 42,300 |
| **World** | 8.7 | 60,500 |

MWRA = married women of reproductive age

**Figure 1. Distribution of IUD Users Worldwide, by Region, 1981**



smaller percentage of all contraceptors now use IUDs (see Table 4) (65). In northern Europe, however, a substantial increase in IUD use occurred in the 1970s.

In China IUD use appears to have increased in the past 10 years. About half of all Chinese contraceptors now use IUDs (72). For the last decade IUD insertions have consistently been the most common of the "four planned birth operations"—which also include vasectomy, tubal ligation, and induced abortion (72). Between 1971 and 1978, 94 million IUDs were inserted (72). In Taiwan, government estimates indicate that about 25 percent of married women are using IUDs (333). A high proportion of married women in Vietnam also are reported to use IUDs—about 27 percent (561).

Surveys indicate little change in IUD use in developing countries, and program statistics suggest no change or possible declines. In 12 developing countries with successive surveys over the last decade—Barbados, Colombia, Costa Rica, Jamaica, South Korea, Mexico, Panama, Paraguay, Singapore, Syria, Thailand, and Trinidad and Tobago—the percentage of women using IUDs remained about the same (see Table 4). In South Korea surveys show a decline in the percentage of contraceptors using IUDs—from 25 percent in 1974 to 18 percent in 1979 (see Table 3). The decline was more than matched by the increase in voluntary sterilization from 14 percent to 38 percent of contraceptors (65, 310).

Service statistics show a mixed pattern. The number of first insertions performed by government family planning programs has declined in Bangladesh, South Korea, and Sri Lanka; remained stable or fluctuated moderately in Indonesia, India, and Taiwan; and remained stable but accounted for a smaller percentage of new contraceptors in Thailand, Mexico, and Egypt (333, 334).

By contrast, in northern Europe surveys of married women show a dramatic increase in IUD use in some countries during the 1970s (see Figure 2). In Finland between 1971 and 1976, IUD use increased ninefold, from 3 to 28 percent. In France, IUD use rose from one percent to 12 percent between 1972 and 1976. In Norway 29 percent of married women used IUDs in 1977, and in Sweden, 16 percent in 1981 (332, 479).

Increasing IUD use in Europe appears to be part of the general modernization of European contraceptive practice. In France, for example, the rise in IUD use was accompanied by a decline in the percentage of married women using withdrawal, from 33 percent in 1972 to 22 percent in 1976, and also by declines in the use of periodic abstinence and condoms. The percentage of married French women using oral contraceptives rose from 11 to 27 percent in the same period (266, 505).

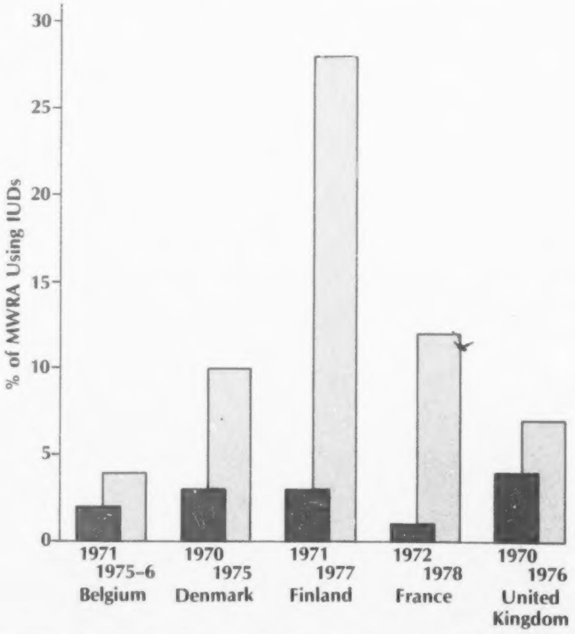
The availability and promotion of several copper IUDs may be responsible for increased IUD use in Europe. In Sweden copper IUDs were introduced in 1972, following publicity about the adverse effects of orals in the late 1960s and early 1970s. It is estimated that the number of Swedish women using IUDs nearly doubled in the year following the introduction of copper IUDs—from 59,000 in 1971 to 103,000 in 1972—and reached 294,000 by 1977 (302).

### Donor Agency Supplies

In most developing countries the great majority of IUDs are supplied by various national and international donor agencies that purchase large quantities at the lowest possible price and ship them to government and private programs. In the last three years about 10 million devices were provided by eight agencies, according to shipment statistics (see Table 5). This figure is consistent with estimates based on survey data of 6.5 million current IUD users in developing countries excluding China. The US Agency for International Development (USAID) supplied 2 million IUDs in 1979 and about half a million in both 1980 and 1981. The United Nations Fund for Population Activities (UNFPA) provided about 2 million to 36 countries in 1981.

USAID supplied nearly 2.9 million IUDs directly to Egypt, Indonesia, and Chile between 1979 and 1981—nearly 90 percent of all USAID IUD shipments in that period—and also supplied smaller quantities of IUDs to 29 other countries. Family

**Figure 2. Increases in IUD Use Among Married Women of Reproductive Age (MWRA) in Europe, 1970–1978**



Sources: Belgium: Cliquet et al. (76, 77); Denmark: United Nations (505), Schmidt (415); Finland: United Nations (505), Riihinen et al. (383); France: United Nations (505), Leridon & Sardon (266); United Kingdom: Bone (44), Dunnell (103).

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## Table 4. Percentage of Married Women of Reproductive Age Using IUDs, as Reported by Representative Sample Surveys, 1970–1981

| Region & Place | Ref. No. | Date of Survey | % Using | | % of Contraceptors Using IUDs[a] |
|---|---|---|---|---|---|
| | | | Any Method | IUD | |
| **AFRICA** | | | | | |
| **Kenya** | 227 | 1977–78 | 7 | 1 | 10 |
| **Lesotho** | 272 | 1977 | 7 | 0 | 3 |
| **Mauritius** | 192 | 1975 | 46 | 2 | 4 |
| **Senegal** | 272 | 1978 | 4 | 0 | 4 |
| **ASIA & PACIFIC** | | | | | |
| **Bangladesh** | 66 | 1975–76 | 8 | 1 | 13 |
| **Fiji** | 66 | 1974 | 41 | 5 | 12 |
| **Hong Kong** | 197 | 1977 | 71 | 3 | 4 |
| **Indonesia** | 66 | 1976 | 26 | 6 | 23 |
| **Korea, Rep. of** | 66 | 1974 | 37 | 9 | 24 |
| | 310 | 1979 | 54 | 10 | 18 |
| **Malaysia** | 66 | 1974 | 33 | 1 | 3 |
| **Nepal** | 66 | 1976 | 2 | 0 | 0 |
| **Pakistan**[b] | 66 | 1975 | 5 | 1 | 20 |
| **Philippines** | 66 | 1978 | 36 | 2 | 6 |
| **Singapore** | 571 | 1973 | 60 | 3 | 5 |
| | 571 | 1977 | 71 | 3 | 4 |
| **Sri Lanka** | 66 | 1975 | 32 | 5 | 16 |
| **Thailand** | 66 | 1975 | 36 | 7 | 19 |
| | 310 | 1978 | 53 | 4 | 8 |
| **LATIN AMERICA & CARIBBEAN** | | | | | |
| **Barbados** | 104 | 1971 | 30 | 3 | 11 |
| | 86 | 1981 | 47 | 4 | 9 |
| **Brazil** | | | | | |
| **Bahía** | 390 | 1980 | 31 | 1 | 2 |
| **Paraíba** | 390 | 1980 | 43 | 0 | 0 |
| **Pernambuco** | 390 | 1980 | 41 | 1 | 1 |
| **Piauí** | 310 | 1979 | 31 | 0 | 0 |
| **Rio Grande do Norte** | 390 | 1980 | 47 | 0 | 1 |
| **São Paulo** | 310 | 1978 | 64 | 0 | 1 |
| **Colombia** | 66 | 1976 | 45 | 9 | 20 |
| | 310 | 1978 | 48 | 8 | 16 |
| | 86 | 1981 | 51 | 8 | 17 |
| **Costa Rica** | 66 | 1976 | 66 | 5 | 8 |
| | 310 | 1978 | 65 | 5 | 7 |
| | 86 | 1981 | 66 | 6 | 9 |
| **Dominican Republic** | 66 | 1975 | 32 | 3 | 9 |
| **El Salvador** | 310 | 1978 | 34 | 3 | 10 |
| **Guadeloupe** | 70 | 1976 | 44 | 3 | 8 |
| **Guatemala** | 310 | 1978 | 18 | 1 | 7 |
| **Guyana** | 66 | 1975 | 31 | 6 | 19 |
| **Haiti** | 204 | 1977 | 27 | 1 | 3 |
| **Honduras** | 86 | 1981 | 25 | 2 | 9 |
| **Jamaica** | 66 | 1975–76 | 40 | 2 | 5 |
| | 310 | 1979 | 55 | 2 | 4 |
| **Martinique** | 70 | 1976 | 51 | 3 | 5 |
| **Mexico** | 66 | 1976–77 | 33 | 6 | 18 |
| | 310 | 1978 | 41 | 7 | 17 |
| **Panama** | 66 | 1976 | 55 | 4 | 7 |
| | 310 | 1979–80 | 61 | 4 | 6 |
| **Paraguay** | 310 | 1977 | 24 | 3 | 14 |
| | 66 | 1979 | 39 | 6 | 15 |
| **Peru** | 66 | 1977–78 | 31 | 1 | 3 |
| **Puerto Rico** | 374 | 1974 | 61 | 4 | 6 |
| **Trinidad & Tobago** | 179 | 1970 | 40 | 3 | 8 |
| | 499 | 1977 | 61 | 3 | 4 |
| **Venezuela** | 521 | 1977 | 60 | 10 | 17 |
| **MIDDLE EAST & NORTH AFRICA** | | | | | |
| **Egypt** | 86 | 1981 | 15 | 2 | 15 |
| **Jordan** | 66 | 1976 | 25 | 2 | 8 |
| **Sudan (North)** | 272 | 1978 | 5 | 0 | 2 |
| **Syria** | 412 | 1973 | 23[c] | 0 | 1 |
| | 272 | 1978 | 23 | 1 | 3 |
| **Tunisia (Jendouba)** | 310 | 1979 | 32 | 7 | 22 |
| **Turkey** | 171 | 1978 | 50 | 4 | 8 |
| **DEVELOPED COUNTRIES** | | | | | |
| **Belgium (Flemish only)** | 76 | 1971 | 88 | 2 | 2 |
| | 77 | 1975–76 | 87 | 4 | 4 |
| **Bulgaria** | 272 | 1976 | 76 | 2 | 2 |
| **Canada** | 64 | 1976 | 62 | 5 | 8 |
| **Czechoslovakia** | 505 | 1970 | 66[c] | 14 | 21 |
| | 272 | 1977 | 95 | 18 | 19 |
| **Denmark** | 505 | 1970[d] | 67[c] | 3 | 4 |
| | 415 | 1975 | 75[c] | 10 | 13 |
| **Finland** | 505 | 1971 | 77[c] | 3 | 4 |
| | 383 | 1977 | 75[c] | 28 | 37 |
| **France** | 505 | 1972 | 64[c] | 1 | 2 |
| | 266 | 1978 | 88 | 12 | 13 |
| **Hungary** | 202 | 1977 | 73 | 10 | 13 |
| **Italy** | 118 | 1976–77 | 77[c] | 3 | 4 |
| | 272 | 1979 | 78 | 14 | 18 |
| **Japan** | 506 | 1974 | 67[c] | 5 | 7 |
| **Netherlands** | 265 | 1975 | 66[c] | 4 | 6 |
| **Norway** | 332 | 1977 | 71[c] | 29 | 39 |
| **Poland** | 505 | 1972 | 57[c] | 1 | 1 |
| | 272 | 1977 | 75 | 8 | 10 |
| **Romania** | 506 | 1978 | 57[c] | 0 | 0 |
| **Spain** | 456 | 1977 | 50 | 1 | 1 |
| **Sweden** | 479 | 1981 | 62[c] | 16 | 26 |
| **UK (England & Wales)** | 44 | 1970 | 75[c] | 4 | 5 |
| | 103 | 1976 | 76 | 7 | 8 |
| **US** | 505 | 1970 | 65[c] | 5 | 7 |
| | 125 | 1973 | 70 | 7 | 10 |
| | 311 | 1976 | 68 | 6 | 9 |
| **Yugoslavia** | 272 | 1976 | 58 | 5 | 9 |

Note: Data from Contraceptive Prevalence Surveys (86, 310, 390) exclude douche, abstinence, and "other" from total contraceptive users; data from World Fertility Surveys (66, 70, 171, 204, 227, 272, 499, 521) include these methods.

Note: Women surveyed are currently in union (Latin America & Caribbean) or married (elsewhere), age 15–44 or 15–49. Exceptions are: **AFRICA**: **Lesotho**, fecund, nonpregnant (includes users of voluntary sterilization); **Mauritius**, ever-married, age <50; **Senegal**, fecund, nonpregnant (includes users of voluntary sterilization); **Sudan**, fecund, nonpregnant (includes users of voluntary sterilization); **LATIN AMERICA & CARIBBEAN**: **Barbados** 1971, all women 15–45; **Costa Rica** 1976, age 20–44; **Haiti**, fecund, nonpregnant (includes users of voluntary sterilization); **Panama** 1976, age 20–44; **Puerto Rico**, ever-married; **Trinidad & Tobago** 1970, ever in union; **Trinidad & Tobago** 1977, fecund, nonpregnant (includes users of voluntary sterilization); **Venezuela**, fecund, nonpregnant (includes users of voluntary sterilization); **MIDDLE EAST & NORTH AFRICA**: **Syria** 1978, fecund, nonpregnant (includes users of voluntary sterilization); **Turkey**, fecund, nonpregnant (includes users of voluntary sterilization); **DEVELOPED COUNTRIES: Belgium** 1971, age 30–34; **Belgium** 1975–76, age 16–44; **Bulgaria**, fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; **Canada**, all women; **Czechoslovakia** 1970, age <50; **Czechoslovakia** 1977, fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; **Denmark** 1970, age 18–49; **Denmark** 1975, age 18–49; **Finland** 1971, age 18–54; **Finland** 1977, in first marriage 18–54; **France** 1972, ever-married, age <45; **France** 1978: fecund (includes users of voluntary sterilization), age 20–44; **Hungary**, age <40; **Italy** 1976–77, all women age 18–64; **Italy** 1976, age 18–64; **Italy** 1979, fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; **Netherlands**, married continuously since 1963–1973, all ages; **Norway**, fecund, nonpregnant (excludes users of voluntary sterilization), age 18–44; **Poland** 1972, age <50; **Poland** 1977, fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45; **Romania**, in first marriage; **Spain**, fecund, nonpregnant (includes users of voluntary sterilization); **Sweden**, all women age 20–44; **UK** 1970, age 16–40; **US** 1970, ever-married, age <45; **Yugoslavia**, fecund, nonpregnant (includes users of voluntary sterilization), in first marriage, age <45.

[a] Figures are not derivable from preceding columns due to rounding.

[b] Pakistan—Respondents were asked about use only after they spontaneously mentioned method in knowledge section of survey.

[c] Excludes sterilization

[d] Denmark 1970—Excludes central municipalities of Copenhagen.

Planning International Assistance (FPIA), with USAID funds, provided nearly one million IUDs, primarily to the Philippines, Mexico, Peru, and Turkey. The International Planned Parenthood Federation (IPPF), largely with USAID funds, provided about 1.6 million IUDs to its affiliated private family planning programs in 80 countries. About half went to Chile and Colombia. The numbers of IUDs sent by UNFPA to specific countries are not available, but India and Vietnam were the major recipients in 1979–81.

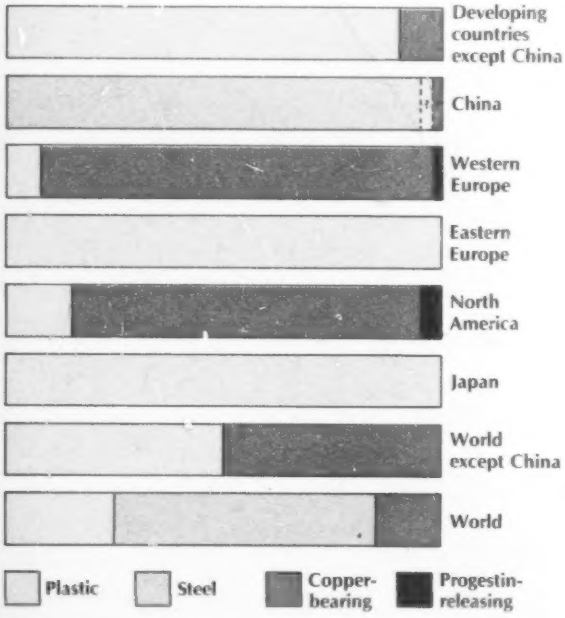
### Types of Devices Used

No data are available on the number of each type of IUD currently in use. Organon International B.V., which manufactures the Multiload through its subsidiary, Multilan S.A., has estimated the 1979 world sales by type of device (see Figure 3). By this estimate, copper IUDs accounted for 80 percent of North American and 90 percent of West European IUD sales, but for only about 10 percent of IUDs sold or distributed in developing countries excluding China (83). Most IUDs in China are stainless steel rings. Small numbers of copper devices and plastic devices are being used in certain areas and studied in clinical trials (72). Plans are being made to produce TCu-220Cs in China (350).

As a result of public sector distribution, the use of copper IUDs in developing countries has probably increased significantly since 1979. The major donor agencies supplying these countries have shipped increasing proportions of copper IUDs in the last three years. USAID, for example, shipped two to three times as many TCu-200 devices as Lippes Loops in 1980 and 1981 (507).

USAID policy is to supply only contraceptives that have been approved by the United States Food and Drug Administration (USFDA) for US use. As of July 1982 the only available devices approved for US use were the Lippes Loop, the Saf-T-Coil, the Cu-7, the TCu-200, and the Progestasert. To date USAID has supplied the Lippes Loop and the TCu-200.

**Figure 3. Estimates of Market Shares by IUD Type, 1979**



Source: adapted from L. Creusen, Organon International B.V. (83)

**Table 5. Deliveries of IUDs by Major Donor Agencies, 1979–1981 (in 1,000s)**

| Region | 1979 | 1980 | 1981 | Total[a] |
|---|---|---|---|---|
| **AFRICA** | | | | |
| USAID bilateral | 30 | 22 | 6 | 58 |
| IPPF | 58 | 97 | 44 | 199 |
| FPIA[b] | 14 | 53 | 44 | 111 |
| Pathfinder | 25 | 29 | 40 | 94 |
| WHO | NA | NA | 50 | 50 |
| SIDA | 11 | — | 110 | 121 |
| Subtotal[a] | 138 | 201 | 294 | 633 |
| **ASIA & PACIFIC** | | | | |
| USAID bilateral | 830 | 339 | 127 | 1,296 |
| IPPF | 30 | 102 | 50 | 182 |
| FPIA[b] | 310 | 165 | 108 | 582 |
| WHO | NA | NA | 32 | 32 |
| SIDA | — | 10 | — | 10 |
| Subtotal[a] | 1,170 | 616 | 317 | 2,102 |
| **LATIN AMERICA & CARIBBEAN** | | | | |
| USAID bilateral | 149 | 107 | 96 | 352 |
| IPPF | 246 | 337 | 534 | 1,117 |
| FPIA[b] | 179 | 26 | 126 | 331 |
| Pathfinder | 207 | 156 | 171 | 534 |
| PAHO | 10 | 165 | 187 | 361 |
| Subtotal[a] | 791 | 791 | 1,114 | 2,695 |
| **MIDDLE EAST & NORTH AFRICA** | | | | |
| USAID bilateral | 1,189 | 126 | 256 | 1,571 |
| IPPF | 35 | 56 | 73 | 164 |
| FPIA[b] | 2 | 272 | 49 | 324 |
| Pathfinder | 4 | 3 | — | 7 |
| WHO | NA | NA | 220 | 220 |
| Subtotal[a] | 1,230 | 457 | 598 | 2,286 |
| **EUROPE** | | | | |
| WHO | NA | NA | 68 | 68 |
| **AGENCY TOTALS** | | | | |
| USAID bilateral | 2,198 | 594 | 485 | 3,277 |
| UNFPA[c] | NA | NA | 2,000[c] | 2,000[c] |
| IPPF | 369 | 592 | 701 | 1,662 |
| FPIA[b] | 505 | 516 | 327 | 1,350 |
| Pathfinder | 236 | 188 | 211 | 633 |
| WHO | NA | NA | 370 | 370 |
| PAHO | 10 | 165 | 187 | 361 |
| SIDA | 11 | 10 | 110 | 131 |
| Total[a] | 3,329 | 2,065 | 4,391 | 9,784 |

Note: USAID bilateral aid is provided directly to national programs. Supplies purchased by USAID also are distributed by FPIA, IPPF, and Pathfinder.

[a] Sum of year columns may not equal total due to rounding.

[b] FPIA figures are for fiscal years.

[c] No regional breakdown is available for UNFPA.

Sources: US Agency for International Development (USAID) (507); United Nations Fund for Population Activities (UNFPA) (28, 264); International Planned Parenthood Federation (IPPF) (60); Family Planning International Assistance (FPIA) (156); Pathfinder Fund (102); World Health Organization (WHO) (320); Pan American Health Organization (PAHO) (455); Swedish International Development Authority (SIDA) (469).

## INSERTION AND REMOVAL

Proper insertion of an IUD is important. Insertion can affect all major events that determine success of use—pregnancy, expulsion, bleeding, pain, perforation, and infection. While there are several different techniques for inserting IUDs, with each the skill of the operator is critical. IUDs can be inserted safely at any time during the menstrual cycle as well as after childbirth or abortion. Expulsion rates are higher after early postpartum insertion but not after first trimester abortion.

Insertion techniques vary depending on the type of device. All IUDs should be inserted as high as possible in the uterine cavity to guarantee the most effective protection against pregnancy and to reduce the likelihood that uterine contractions will cause expulsion. The Lippes Loop is inserted by the "push-out" technique. The tube containing the device is inserted in the uterus about 4.5 cm beyond the external cervical os, and the IUD is pushed out by a plunger. Copper devices such as the TCu-200 use the withdrawal technique. The tube containing the device is inserted up to the uterine fundus. The tube is withdrawn while an inner rod holds the IUD in position. Then the rod is withdrawn. The Multiload and Progestasert are inserted like the T devices, but the inserter tube does not contain an inner rod. In the case of these two IUDs, the arms of the device do not fit within the tube but are pressed against the outside of the tube as it passes through the cervix. The withdrawal method is thought to cause fewer fundal perforations than the "push-out" technique (25, 211, 392, 475, 511). (See box, p. B-115.)

### Timing of Interval Insertion

Established practice has been to limit insertion of IUDs in women who are neither postpartum nor postabortion to during or shortly after menses, because insertion was thought to be easier and safer at that time (543). This restriction is not justified. Recent studies of about 10,000 women show that there is no one preferable time for insertion (106, 542). In a US study, when IUDs were inserted after the 18th day of the cycle, rates of pregnancy and removal for bleeding and pain were higher, but rates of expulsion and pelvic infection were lower than with insertion around the time of menses. Rates for other medical removals during the first two months after insertion were lowest when IUDs were inserted from the 11th to the 17th day of the cycle (542). All differences were small, however. Another study found no differences in event rates whether IUDs were inserted during menses or at any other time (106). Thus, for a woman who is reasonably sure she is not pregnant, the best time to insert an IUD is when she comes to a health center to request it.

### Postpartum Insertion

For women who deliver in hospitals or health centers, IUD insertion in the early postpartum period (after delivery but before discharge) is a safe and convenient procedure. The risks of infection, perforation, or heavy bleeding are no greater than at

**Table 6. Performance of IUDs After Immediate Postpartum Insertions, Selected Studies, 1980–1982**

| Author, Date, & Ref. No. | Place | Devices Studied | No. of Women | Event Rates (per 100 Women) | | | | | Continuation Rate |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Accidental Pregnancy | Expulsion | Bleeding /Pain | Infection | Other Medical | |
| **6-MONTH RATES** | | | | | | | | | |
| **Aznar et al. 1980** (27) | Mexico | Various standard IUDs | 1,008 | 0.4 | 17.5 | 3.4 | 0.9 | 0.5 | 75.6 |
| **IFRP 1981** (209) | 19 countries | Delta Loop (modified Lippes Loop D) | 2,908 | 0.5[a] | 13.7[a] | 2.5[a] | 0.9[a] | | NA |
| | | Delta T (modified TCu-220C) | 1,549 | 0.1[a] | 10.6[a] | 4.4[a] | 1.3[a] | | NA |
| **Sobrevilla et al. 1980** (451) | Colombia | TCu-220C | 274[b] | 0 | 2.3 | 3.0 | | | 92.8 |
| | | Lippes Loop | 522[b] | 0.8 | 5.9* | 2.8 | | | 88.3 |
| **Thiery et al. 1980** (492) | Belgium | TCu-200 | 269 | 0 | 9.4[a] | 0.8[a] | 0 | 0.4[a] | 85.0 |
| | | Multiload-cu 250 | 293 | 1.5[c] | 7.4[a] | 1.0[a] | 0 | 0.4[a] | 88.8 |
| **WHO 1980** (553) | Belgium, Chile, El Salvador, Hungary, UK, West Berlin | Lippes Loop | 272 | 7.3 | 41.3[c] | 3.5 | 6.7 | | 48.1 |
| | | TCu postpartum | 287 | 1.6 | 39.4[c] | 3.5 | 4.0 | | 54.6 |
| | | Cu-7 | 282 | 1.3 | 31.1[c] | 1.8 | 0.9 | | 64.6 |
| **12-MONTH RATES** | | | | | | | | | |
| **Aznar et al. 1980** (27) | Mexico | Various standard IUDs | 1,008 | 2.8 | 23.5 | 5.5 | 1.2 | 0.7 | 61.8 |
| **Sobrevilla et al. 1980**[a] (451) | Colombia | Lippes Loop | 274[b] | 1.9 | 7.8* | 3.4 | | | 82.1 |
| | | TCu-220C | 522[b] | 1.7 | 3.6 | 5.3 | | | 82.0 |
| **Thiery et al. 1980** (492) | Belgium | TCu-200 | 269 | 0.5[a] | 11.2[a] | 1.8[a] | 0 | 0.4[a] | 77.2 |
| | | Multiload-cu 250 | 293 | 2.4[a] | 9.9[a] | 3.6[a] | 0 | 0.9[a] | 77.3 |
| **Thiery & Van der Pas 1982** (490) | Belgium | TCu-200 | 136 | 3.4 | 5.2 | 5.7 | 0 | 0 | 82.2 |
| | | Multiload-cu 250 | 135 | 1.8 | 3.1 | 2.4 | 0 | 0 | 88.6 |
| | | Multiload-cu 375 | 134 | 0 | 4.6 | 4.8 | 0 | 0.8 | 84.4 |
| **WHO 1980** (553) | Belgium, Chile, El Salvador, Hungary, UK, West Berlin | Lippes Loop D | 272 | 12.1 | 44.1[c] | 4.6 | 9.0 | | 39.1 |
| | | TCu postpartum | 287 | 5.6 | 41.3[c] | 8.7 | 5.0 | | 46.9 |
| | | Cu-7 | 282 | 7.2 | 34.8[c] | 5.2 | 1.8 | | 52.3 |

NA = not available

*Reported as statistically significant; not all studies report tests of significance.

[a] Gross rates; all other studies report net rates.

[b] 14% of TCu-220C and 12% of Lippes Loop insertions were postabortion; remainder were one to 91 + days postpartum.

[c] Excludes 37 women whose IUDs were expelled within first 48 hours.

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## WHAT THE IUD USER SHOULD KNOW

For many women the IUD is an excellent contraceptive. It is highly effective and does not require day-to-day action such as taking a pill or monitoring signs of fertility. During breastfeeding, unmedicated and copper IUDs do not affect milk volume or composition. IUDs are not appropriate for all women, however. The risks of PID, ectopic pregnancy, and, in some cases, subsequent infertility are greater than with other methods. Thus every potential IUD user needs informed and sympathetic counseling telling her what the risks and benefits are and how they may apply to her.

Medical contraindications to IUD use, as listed in the 1981 IPPF Medical Policy Statement, include:

- current or past PID,
- known or suspected pregnancy,
- history of ectopic pregnancy,
- gynecological bleeding disorders before the establishment of a definitive diagnosis,
- suspected malignancy of the genital tract,
- congenital uterine abnormalities or fibroids that prevent proper IUD placement (211).

Other medical factors that might contraindicate IUD use, depending on individual circumstances and the judgment of health care personnel and potential user are:

- anemia,
- nulliparity,
- blood coagulation disorders,
- severe cervical stenosis,
- heavy menstrual flow,
- severe primary dysmenorrhea,
- for copper-bearing IUDs, copper allergy or Wilson's disease (a rare inherited disorder of copper excretion) (211).

For the nulliparous woman who plans to have children eventually, IUD use raises special issues. IUD users are more likely to develop PID than other women, and every episode of PID carries some possibility of tubal obstruction and infertility. For this reason many clinicians believe that nulliparous women should not use IUDs (115, 183, 198, 316, 450). In any case, nulliparous women should receive special counseling before they choose an IUD (49, 504). All women should know that the risk of contracting PID is greatest for those who are young, have multiple sexual partners, and are frequently exposed to sexually transmitted diseases. Each woman can then consider whether the benefits of IUD use outweigh the risks.

Women with diabetes may also need special attention if they use an IUD. Some studies have reported higher pregnancy rates and different endometrial reactions among diabetic women using IUDs (149, 250, 464), while others have found no difference (260, 544). The Medical Advisory Panel of IPPF and the National Family Planning Association of Great Britain concluded, after reviewing research results, that diabetes is not a contraindication to IUD use (82, 211).

In addition, a woman using an IUD should know:

- how to check for IUD strings and to return for follow-up care if she cannot locate the strings or if she misses a period,
- common side effects of IUD use such as increased bleeding and cramping,
- the need to seek medical attention if any signs or symptoms of infection appear—fever, pelvic pain and tenderness, unusually heavy bleeding, severe cramping, or heavy discharge,
- the fact that pregnancy with an IUD in place may be ectopic and that abdominal pain and amenorrhea can be signs of ectopic pregnancy,
- that if pregnancy occurs with an IUD in place, even if a woman wants to continue her pregnancy, she should seek medical attention. The device should be removed immediately if possible. If not possible, she should be warned of the risk and symptoms of septic abortion,
- the type of IUD,
- the recommended time for replacement of a medicated IUD.

IUD users should be reexamined within three months after insertion, if possible, to ensure proper placement of the device. Annual checks also are useful to be sure the device is still properly placed. Women who have passed menopause should have their IUDs removed, since narrowing and shrinking of the uterus may make later removal difficult (225).

Unmedicated IUDs can be used for long periods of time, but devices with 200 square mm of copper have a manufacturers' recommended lifetime of only two to three years. The IUDs with more copper have longer lifespans, and the Progestasert has a one-year lifespan. If a woman has forgotten which IUD she has and when it should be replaced, the color of the cervical threads may give some clue (see descriptions, pp. B-118–120), but colors have not been standardized, and some manufacturers may change thread color.

Regulatory agencies have cautiously limited manufacturers to recommending lifespans of several years at most. Nevertheless, copper IUDs they may be effective longer (see p. B-107). Thus routine removal and reinsertion after three years may in fact not provide greater protection against pregnancy but instead may expose the user to the higher risk of PID, perforation, and other complications that occur most frequently soon after insertion. Two devices particularly associated with serious problems, the Dalkon Shield and the Mazlin Spring, should be removed in any case and replaced by other devices or other forms of contraception.

six weeks after childbirth or at a time unrelated to pregnancy (30, 208, 392, 393, 488). Expulsion rates tend to be high, however. In Santiago, Chile, the 3-month expulsion rate for 1,142 women fitted with TCu-200s between eight hours and six days after delivery was 32 compared with 5 to 15 for interval insertion (see p. B-103) (259). IUDs inserted immediately after delivery of the placenta are also frequently expelled. In a WHO multicenter trial the 12-month expulsion rates following postplacental insertion were 44 for the Lippes Loop D and 35 per 100 women for the Cu-7 (553) (see Table 6).

To try to minimize expulsions, both the International Fertility Research Program (IFRP) and the Population Council have modified IUDs especially for postpartum insertion. IFRP has modified the Lippes Loop D and the TCu-220C (calling them the Delta Loop and Delta T) by attaching chromic catgut sutures to the upper arms of the devices. It was expected that the sutures would embed in the endometrium and hold the device in place during uterine involution. The sutures slowly dissolve in the uterus over a 6-week period (206, 257). In randomized trials of postplacental insertion comparing the modified devices with standard devices, the Delta Loop had a significantly lower 6-month expulsion rate than the standard Loop—16 versus 22. By contrast, the expulsion rates for the Delta T and the unmodified TCu-220C were very similar—both about 12 (78). IFRP is currently developing new models of the Delta Loop and Delta T with projections made of a slowly biodegradable copolymer. These projections are expected to keep their shape and strength in utero better than catgut sutures (541) (see photo, this page).

The Population Council has developed the Postpartum T, a T-shaped copper-bearing device with additional arms extending 2 cm upward and outward from the lower end of the stem. A WHO trial reports a high 12-month expulsion rate of 41 (553).

Careful postpartum insertion technique may be more important in reducing expulsions than the design of any particular IUD (see box, p. B-115). For example, in seven centers where IFRP researchers performed 1,350 postplacental insertions of the Delta Loop or Delta T, 3-month expulsion rates ranged from zero to 19 per 100 (78). This wide variation suggests differences in insertion technique and skill. Earlier studies documented similar variation among centers with interval insertions (39, 40, 304). Some investigators—Michael Thiery, for one—report low expulsion rates regardless of the device or the time of insertion (488, 490, 492). In a WHO multicenter trial of postplacental insertion, the Santiago, Chile, center reported the lowest expulsion rates. At that center manual examination was performed after each insertion. If the device was palpable, and thus incorrectly placed, it was immediately removed and reinserted (553).

It is not clear whether insertion by hand or with instruments leads to better placement. When manual insertion was compared with insertion using a special 30 cm-long flexible inserter, there was no difference in expulsion rates (78, 258).

Unpublished data suggest that risk of uterine perforation may be greater in lactating women than in nonlactating women when IUDs are inserted at approximately six weeks or more after delivery (462). Although confirmation of this finding is necessary, it suggests that lactating women may require special attention in using IUDs, as they do in using steroidal contraception (see **Population Reports**, *Breast-Feeding, Fertility and Family Planning*, J-24, November–December 1981).

**An IUD with a new modification especially for postpartum insertion has been developed by IFRP. Projections made of a slowly biodegradable copolymer on the arms of a TCu-380Ag are intended to help keep the device in place during uterine involution.**

### Postabortion Insertion

IUDs can be inserted immediately after first trimester spontaneous or induced abortion. Recent studies in both developed and developing countries confirm earlier findings that infection, perforation, expulsion, bleeding, and pregnancy rates are no higher when IUDs are inserted after first trimester abortion than after interval insertions (20, 74, 143, 231, 382, 516, 551, 568). IUDs inserted after second trimester abortions, however, are 5 to 10 times more likely to be expelled than after first trimester abortion, according to a recent WHO multicenter trial (551).

Comparative studies suggest that event rates after postabortion insertion differ among devices. Complications were more frequent with the Lippes Loop than with the TCu-200, TCu-220C, and Cu-7 in several studies (74, 143, 231, 395, 551) (see Table 1, p. B-104). In the WHO trial, however, the 2-year expulsion and pregnancy rates for the Lippes Loop D were significantly higher than the rates for the TCu-220C but similar to the rates for the Cu-7. Based on these results, the WHO Special Programme of Research, Development and Research Training in Human Reproduction recommends the TCu-220C for postabortion use (551).

### Postcoital Insertion

IUD insertion shortly after one or more acts of unprotected intercourse may prevent pregnancy by interfering with the implantation of the fertilized ovum in the uterus (42, 150, 276, 503). No pregnancies occurred after insertion of the Cu-7 in 42 women up to five days after unprotected intercourse. Hormonal studies indicated that fertilization had occurred in 15 of the women (503). In a study of 299 women, no pregnancies were observed after postcoital insertion of the TCu-200 or Cu-7. Insertions took place up to seven days after unprotected intercourse (276). Postcoital IUD insertion does not produce the side-effects of nausea and vomiting that often occur with postcoital use of hormones, although, where genital infection is present, it may increase the risk of pelvic inflammatory disease (PID) (150, 162, 368, 370). Postcoital insertion offers the advantage of providing an effective continuing method of contraception (398). IPPF is now recommending postcoital insertion of copper IUDs when "there is concern about the oral administration of oestrogen-containing preparations. . ." (211).

### Measuring the Uterus

Some researchers believe that pregnancy, expulsion, heavy bleeding, and pain can be minimized by more careful measurement of the endometrial cavity and selection of the appropriately sized IUD (6, 11, 181, 241, 242, 495). Several small studies report that side-effects are more frequent in women whose uterine measurements are outside the normal range of about 6.5 to 8 cm from the external os to the fundus (11, 135, 220, 247, 486). New instruments have been developed to measure more precisely the length of the endometrial cavity—the Hasson Wing Sound I (6, 180, 181)—and both length and width—the Hasson Wing Sound II and the Cavimeter (6, 182, 241, 495). The usefulness and practicality of these instruments for developing country programs is not clear. Although more accurate measurement could identify women with very small or very large uterine cavities, who would be

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# Instructions for IUD Insertion

With all IUDs, manufacturers' instructions for insertion should be followed exactly. IUDs and instruments inserted into the endocervical canal and uterus should be sterile. The following steps are recommended in the 1978 US Food and Drug Administration's *Second Report on Intrauterine Devices* (511):

1. Administer analgesics and sedatives if needed. Use atropine if there is reason to expect syncope (temporary loss of consciousness). For parous women IUD insertion usually involves brief discomfort rather than pain, but there is great individual variation.

2. Insert a speculum into the vagina and inspect the cervix and vaginal walls.

3. If possible, take a Papanicolaou cervical smear and a culture for gonorrhea.

4. Perform a bimanual examination to determine the size, shape, position, and mobility of the uterus and to rule out malignancy or inflammation of adjoining organs.

5. Reinsert the speculum and swab the endocervix and vaginal walls with an antiseptic solution.

6. Use intracervical anesthesia or a paracervical block at this time if necessary. This may be helpful for nulliparous women, women with cervical stenosis, or women who may experience syncope.

7. Place a tenaculum on the cervix and apply gentle traction to straighten and stabilize the uterus. This will minimize bleeding and risk of perforation.

8. Insert a uterine sound to determine the direction and size of the endocervical canal and internal os and the position and depth of the uterus. Sounding should be done gently to avoid perforation. If any obstruction is encountered, the IUD should not be inserted. If the uterus is smaller than 6.5 cm in depth, consider using a smaller than standard IUD.

9. Insert the IUD, following the manufacturer's instructions, up to the uterine fundus, with only the strings remaining in the endocervical canal. An IUD should not remain in the inserter tube longer than two minutes or the IUD will not resume its shape.

### IFRP Instructions for Postpartum Insertion

The International Fertility Research Program (IFRP) recommends the following technique for immediate postplacental insertion of an IUD in its clinical trials (207):

1. Grasp the anterior lip of the cervix at the 12 o'clock position with a sterile ring forceps (ovum or sponge-holding forceps) (see Figure A).

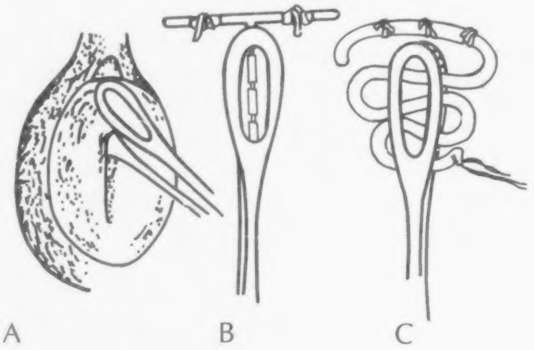
2. With a second sterile ovum or ring forceps grasp the IUD (see Figures B and C) and close the lock of the forceps. Slip the distal portion of the string between the fourth and fifth fingers to keep the string straight.

3. Insert the IUD through the cervical canal. When the IUD reaches the fundus, the operator will feel resistance. Place one hand on the abdomen and palpate the fundus to confirm that the IUD is placed as high in the uterine cavity as possible.

4. Once the IUD has reached the fundus, release the ring forceps that holds the IUD, separate the blades, and gently withdraw the forceps from the uterine cavity. During this procedure the strings of the IUD should not move. If more of the strings becomes visible, the IUD has dropped from its fundal placement. It *must* then be removed and reinserted.

5. Following removal of the ring forceps that held the IUD, release the ring forceps that has been grasping the cervix.

6. Trim the strings 1.5 cm from the external os.



more likely to experience side effects, the measuring devices are expensive and not designed for reuse (495). In addition, health centers may not have a wide range of IUDs available, and only a few devices come in several sizes.

### Removal

Usually IUDs can be easily removed by pulling on the strings. Sometimes problems occur, however. When the strings are not visible or when perforation is suspected, clinicians have several options. Many IUDs in the uterus can be removed with simple hooks, alligator forceps, or other forceps with narrow jaws (13, 21, 159, 187, 427, 487) (see photo, p. B-126). Threads that have been drawn into the uterus can be retrieved by vacuum aspiration (161, 167, 233). If these methods fail, or if the device has perforated the uterus, curettage or other surgical procedures such as laparotomy or laparoscopy may be necessary to remove it (167, 431, 504).

If facilities are available, diagnosis of uterine perforation can usually be confirmed by hysterography (x-rays of the uterine cavity after instillation of a contrast medium), by hysteroscopy (direct visualization of the uterine cavity with a fiberoptic instrument), or by ultrasound techniques. Otherwise, inserting a sound or a second IUD into the uterine cavity and taking lateral and anteroposterior x-rays of the pelvis can help to locate a displaced device by making clear the position of the uterus (see photo, p. B-116) (25, 167, 187, 303, 566).

Some devices should be removed promptly when they are found outside the uterus. Copper devices cause severe adhesions (25, 233, 344, 373, 476, 504, 566). Closed devices such as the ring or bow are more likely than others to obstruct or perforate the bowel (233). IPPF and others favor removal of progesterone devices as well, since they can produce intraperitoneal irritation (162, 233). With regard to open, unmedicated IUDs such as the Lippes Loop and Saf-T-Coil, some researchers believe that they should be removed to avoid potential complications if they are found outside the uterus (25, 106, 229, 454, 566). Others suggest that they can remain in the abdominal cavity as long as the user has no symptoms (233, 275).

### Insertion by Nurse-Midwives and Paramedicals

Nurse-midwives and paramedicals can master the technical skills necessary for IUD insertion. They may also establish a close rapport with clients that can improve acceptance of IUDs (109, 247, 279, 300, 349, 378, 433, 551, 559, 567, 569). Recent WHO studies in the Philippines and Turkey found that nurse-midwives and physicians were equally able to identify contraindications and complications of IUD use and that expulsion, pregnancy, and removal rates were similar after insertion by nurse-midwives and by physicians (551). In China female barefoot doctors in every commune routinely insert and remove IUDs (572).

Female paramedical personnel may increase the acceptance of IUDs because women in many cultures prefer these workers to male physicians (14, 380, 413). These women also tend to be more accessible to clients. The WHO study in the Philippines found that, although expulsion rates after insertion by nurse-midwives and physicians were similar, nurse-midwives performed reinsertions for 55 percent of their clients who expelled IUDs, compared with the physicians' 31 percent. The nurse-midwives were more successful because they followed up their clients more frequently than physicians (551).

In some countries auxiliary health personnel are now performing insertions in women's homes. In the Philippines over 60 percent of the IUD insertions performed by health personnel of the Bohol project were done in clients' homes (413).

Training programs for paramedical personnel are now being developed and evaluated. After reviewing the results of two small programs in the Philippines and Turkey, A. Akin and colleagues made the following recommendations for other training programs:

- A technical reference manual adapted to local needs should be used as the basis for the training program.
- Teaching physical examination and IUD insertion is most successful with a ratio of two or three trainees per instructor.
- The training should focus on management of normal cases, but all trainees should be given very clear criteria for recognizing contraindications and complications of IUD use.
- Trainees should perform at least 50 to 60 supervised pelvic examinations before working on their own.
- Trainees should perform at least 10 to 15 IUD insertions under supervision (14).

The programs in the Philippines and Turkey have now been expanded, and further evaluation of training, performance, and the extent of supervision needed is underway (552).

**Women choosing a contraceptive method need accurate and sympathetic counseling in terms they can understand. A pamphlet designed by PIACT de México to explain IUD use to nonliterate women shows that the IUD fits in the uterus as if in a pear.**

## BLEEDING

Increased bleeding, often accompanied by pain in the lower abdomen or lower back, is the most frequent problem of IUD use. Roughly 5 to 15 percent of women have their IUDs removed within the first year because of bleeding and pain. Three types of bleeding changes occur:

- greater volume of menstrual blood flow,
- longer menstrual periods,
- midcycle, or intermenstrual bleeding or spotting.

These changes may cause both inconvenience and possible health risks for IUD users.

Both copper and unmedicated IUDs increase the volume of blood loss during menses, but copper devices cause less increase. Normal menstrual blood loss in healthy women averages about 35 ml per cycle (178, 212, 538). With unmedicated devices, blood loss approximately doubles compared with preinsertion levels. Average increases range from 20 to 50 ml (132, 165, 166, 170, 190, 191, 212). With the Cu-7 and TCu-200 devices, blood loss increases by about 50 percent, or 10 to 30 ml, above preinsertion levels (166, 191, 212, 249, 270, 271, 290). The smaller increase in blood loss is probably because of the smaller surface area of these devices, not the addition of copper (164, 191). Heavy blood loss—over 80 ml—also occurs less frequently with copper IUDs than with unmedicated IUDs. In a British study 25 percent of the Cu-7 users experienced heavy blood loss compared with 50 to 60 percent of the Lippes Loop users. Before insertion 10 to 15 percent of all women experienced heavy blood loss (166, 309).

Unlike unmedicated and copper IUDs, progestin-releasing devices reduce the volume of blood loss by as much as 40 percent (110, 164, 284, 285, 329, 406). In fact, the experimental devices with higher doses of progestin cause amenorrhea in some women (284, 327, 329). In several studies the Progestasert also reduced the incidence of dysmenorrhea (painful menstruation) by as much as one-third (136, 565, 591), and the levonorgestrel IUD, which releases 20–30 mcg per day, even more (283). A recent WHO study, however, found no significant difference between the Cu-7 and the Progestasert in the reduction of dysmenorrhea (361).

All IUDs tend to prolong menstrual bleeding, often in the form of spotting, or very light bleeding (565, 591). Copper devices may prolong menstrual bleeding more than unmedicated devices. In a group of parous British women, for example, the sixth menstrual period after insertion lasted on average 1.2 days longer than before IUD insertion for Cu-7 users. For Lippes Loop users, the sixth postinsertion menstrual period lasted 0.4 days longer—an 8 percent increase. Adding copper to the Lippes Loop lengthened the duration of flow by two days—a 36 percent increase over preinsertion levels (164).

Progestin-releasing devices, while reducing the volume of blood loss, increase the total number of days of bleeding and the incidence of midcycle bleeding even more than other devices (164, 188, 244, 397, 511). This difference may decrease with length of use (188, 329, 554). An increase in the number of days of bleeding may be less acceptable to women than an increase in the volume of bleeding (555, 556). In four of five comparative trials, removal rates for bleeding and pain with progestin-releasing IUDs were similar to or higher than with copper or unmedicated devices (131, 244, 284, 329, 362, 554).

### Risk of Anemia

The most serious problem that may result from increased menstrual blood loss is iron-deficiency anemia. About 50 percent of nonpregnant women in developing countries are already anemic (549), and many more are on the borderline. Repeated pregnancies contribute to anemia in many women. While common sense suggests that increased menstrual blood loss could lead to anemia or make existing anemia worse, studies designed to evaluate the impact of IUDs on iron levels have not produced conclusive results. In Malaysia, Mexico, and Chile studies 6 and 12 months after IUD insertion showed declines in transferrin saturation and serum ferritin levels (140, 551)—signs of iron loss—and declines in hemoglobin (132, 140) and hematocrit (123)—signs of iron deficiency. Several other studies, however, in India and Latin America, found no change in various indicators of anemia after 12 months of use (123, 366, 371, 385, 386, 584). These studies involved women using unmedicated and copper devices (366, 385, 386) and, in Mexico, women already moderately anemic (385, 386). By contrast, among women using progestin-releasing devices, hemoglobin and average serum ferritin levels increased compared with preinsertion levels (188, 324, 385, 386, 551).

In developed countries, where anemia is much less prevalent, researchers also report conflicting results. Some studies show a decline either in plasma ferritin or in hemoglobin levels after IUD insertion (63, 163, 165, 212, 309, 404), while others show no effect (249, 270). Recently a US case-control study of almost 4,000 women found that IUD users were at no greater risk of being hospitalized for severe vaginal bleeding than women using barrier methods or no method. Among those hospitalized for heavy bleeding, those who were anemic were no more likely to use IUDs than those who were not anemic (200).

### Limiting Bleeding

Why IUDs cause increased menstrual bleeding is not completely clear. Mechanical stress to the endometrium caused by pressure from the IUD or by distortion or displacement of the device may interfere with the normal blood clotting mechanisms of the endometrium (106, 220, 315, 428). Insertion of an IUD leads to a higher concentration of plasminogen activators (enzymes that break down proteins and activate the dissolution of blood clots) in the endometrium. These enzymes increase fibrinolytic activity and prevent blood clotting, leading to greater blood flow (46, 106, 189, 249, 251, 252, 271, 404, 428). There is some evidence that menstrual bleeding in IUD users begins early—several days before the end of the luteal phase. This may be because the endometrium in an IUD user is less sensitive to progesterone and thus begins to slough off before progesterone levels decline to the point that normally leads to menstruation in nonusers. Ovarian function is unchanged, however (51, 122, 293, 335).

## MECHANISMS OF ACTION

Even though IUDs have been widely used for over 20 years, the precise mechanisms by which they prevent pregnancy are still unknown. In animals the mode of action of an IUD varies from one species to another (511). In humans several different mechanisms of action appear to be at work.

All IUDs stimulate an inflammatory, or foreign-body response in the uterus, which in turn causes cellular and biochemical changes in the endometrium and uterine fluids. These changes are believed to be responsible for the contraceptive effect (174, 234, 511). After IUD insertion numerous polymorphonuclear leukocytes appear in the endometrium and uterine fluids, followed by foreign-body giant cells, mononuclear cells, plasma cells, and macrophages (168, 312, 313, 408, 409). These cells may consume the spermatozoa or the fertilized ovum by the process of phagocytosis.

Another theory, not necessarily incompatible, is that changes in the endometrium, perhaps stimulated by the inflammatory reaction, delay the normal cyclic changes of the endometrium, making it inhospitable to implantation at the time the fertilized ovum arrives (47, 195, 216, 426, 560, 564). No evidence has emerged, however, that unmedicated or copper IUDs cause any fundamental changes in hormonal function (173, 234, 367).

Medicated IUDs, in addition to producing an inflammatory reaction, have local effects that may play a part in their contraceptive action. While copper affects the uterus, its precise role in preventing pregnancy is not known. Copper interferes with enzymes in the uterus (347), with the amount of DNA in endometrial cells (174), with glycogen metabolism (389), and with estrogen uptake by the uterine mucosa. Copper increases the inflammatory reaction (307) and may increase contractions of the uterine muscle layer, thus preventing implantation (254). Also, copper ions alter the biochemical composition of cervical mucus. This may affect sperm motility, capacitation, or survival (23, 222, 234, 379).

IUDs containing progesterone interfere with the normal hormone-regulated cycle of the endometrium (357, 418). By maintaining high progesterone levels in the uterus and, consequently, relatively low estrogen levels, these devices keep the endometrium in a state in which implantation is unlikely to occur (419). The small amount of progesterone released by Progestaserts—65 mcg per day—seems not to affect the ovaries and is not detectable in blood serum (419). By contrast, IUDs releasing an even smaller amount of the stronger synthetic progestin levonorgestrel—12 mcg per day—sometimes prevent ovulation (327).

Research is underway to identify drugs that will reduce menstrual bleeding when administered either orally or through the

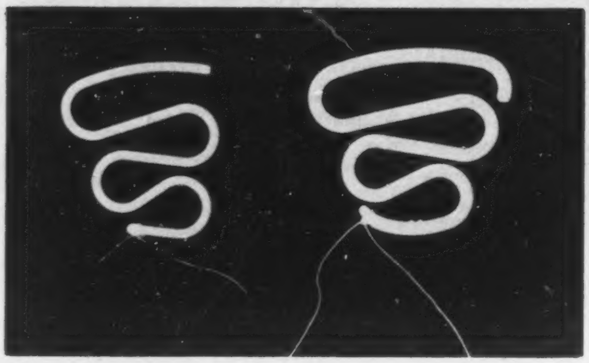


**Figure 4. Lippes Loop**

**Description:** One of the first of the modern IUDs and for years the standard, the Lippes Loop is the most widely used IUD in developing countries outside of China. Injection-molded of alathon-20 polyethylene, it comes in four types, the smallest designated A (left); the largest, D (right). The Loop was the first IUD to incorporate barium sulfate for radiopacity and the first IUD to have a tail.

**Developer:** Jack Lippes (US)

**Date marketed:** 1962

**Distributors:** Finishing Enterprises, US; Ortho Pharmaceutical Corporation, US.

**Length:** A, 26.2 mm; B, 25.2 mm; C, 27.5 mm; D, 27.5 mm.

**Width:** A, 22.2 mm; B, 27.4 mm; C, 30.0 mm; D, 30.0 mm.

**Tail:** Two threads; A, blue; B, black; C, yellow; D, white.

**Inserter type:** Push-out

**Inserter diameter:** 4.7 mm

**Areas of major use:** Worldwide

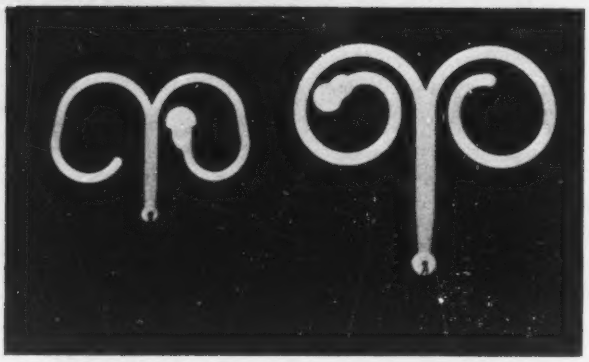


**Figure 5. Saf-T-Coil**

**Description:** Injection-molded of ethylene vinyl acetate copolymer with barium sulfate added for radiopacity, the Saf-T-Coil comes in three sizes, the 25-S (left), the 32-S (not shown), and the 33-S (right).

**Developer:** Ralph R. Robinson (US)

**Date marketed:** 1965

**Distributor:** Schmid Laboratories, US

**Tail:** Two green threads

**Length:** 25-S, 20 mm; 32-S, 30 mm; 33-S, 32 mm.

**Width:** 25-S, 25 mm; 32-S, 29 mm; 33-S, 37 mm.

**Inserter type:** Retract over plunger

**Inserter diameter:** 25-S, 3.76 mm; 32-S and 33-S, 4.5 mm.

**Areas of major use:** Worldwide

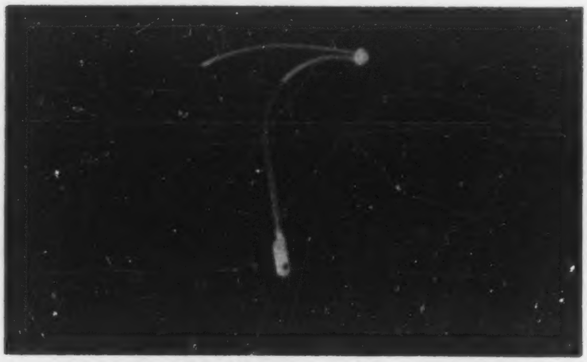


**Figure 6. Cu-7, or Gravigard**

**Description:** The Cu-7 has copper wire with a surface area of 200 square mm wrapped around its stem. The plastic component is injection-molded of polypropylene homopolymer with barium sulfate added for radiopacity.

**Developers:** Jaime Zipper and Harvey Abramson (Chile)

**Date marketed:** 1974

**Distributor:** G.D. Searle & Company, US

**Length:** 36 mm

**Width:** 26 mm

**Tail:** One blue thread

**Effective life:** USFDA-approved, 3 years

**Inserter type:** Withdrawal type; can be used for push-out insertion if desired.

**Inserter diameter:** 3.07 mm

**Areas of major use:** Australia, Canada, Europe, Mexico, US

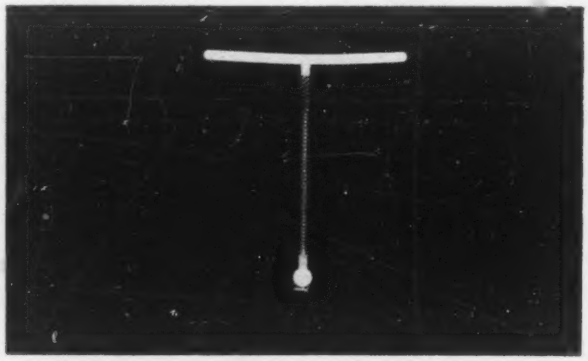


**Figure 7. TCu-200, or Gyne T, and TCu-200B**

**Description:** Injection-molded of polyethylene with barium sulfate added for radiopacity, this device was the first medicated IUD tested for contraceptive use. The copper wire wrapped about the stem of the IUD exposes 200 square mm of surface area. The TCu-200B has a ball at the tip of the stem; the TCu-200 does not (not shown).

**Developers:** Howard Tatum (US) and Jaime Zipper (Chile)

**Date marketed:** 1972

**Distributors:** Finishing Enterprises, US; G. D. Searle & Co., US; AB Kabi, Sweden; Huhtamaeki Oy, Leiras Pharmaceuticals, Finland; Outokumpu Oy, Finland; Ortho Canada; Ortho Pharmaceutical, Ltd., UK; Schering AG, West Germany.

**Length:** 36 mm

**Width:** 32 mm

**Tail:** Two threads; color varies.

**Effective life:** USFDA-approved, 3 years

**Inserter type:** Withdrawal

**Inserter diameter:** 4.4 mm

**Areas of major use:** Worldwide

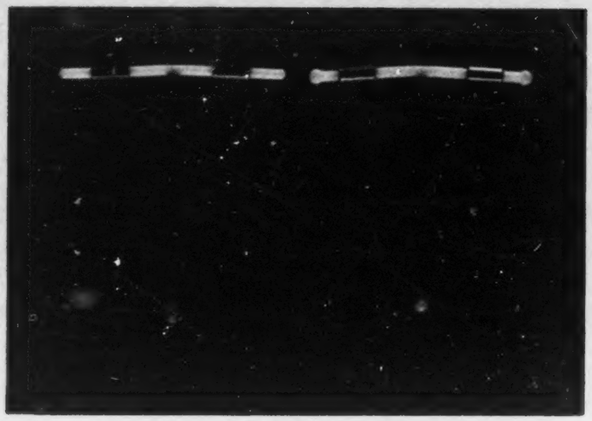


**Figure 8. TCu-220C and T modified 220 Cu, or Cobritec**

Description: Of the same T shape as the TCu-200, the TCu-220C has seven solid copper collars, or sleeves—two on the transverse arm and five on the stem. With a total exposed copper surface of 220 square mm, this device has a longer effective life than the TCu-200. The T modified 220 Cu (right) has an enlarged round end on the bottom of the stem and on the two transverse arms.

Developer: Population Council

Date marketed: 1980

Distributors: Promotora e Importadora PEISA, Mexico; Biotec Laboratories, Mexico (modified version).

Length: 36 mm

Width: 32 mm

Tail: Two threads; TCu-220C, blue or white; T modified 220 Cu, translucent.

Inserter type: Withdrawal. (A new inserter being introduced for the T modified 220 Cu will allow personnel to load and cock the inserter without touching the IUD.)

Inserter diameter: TCu-220C, 4.4 mm; T modified 220 Cu (old inserter), 4.7 mm; T modified 220 Cu (new inserter), 4.5 mm.

Effective life: Developer's estimate, 15-20 years

Areas of major use: Mexico

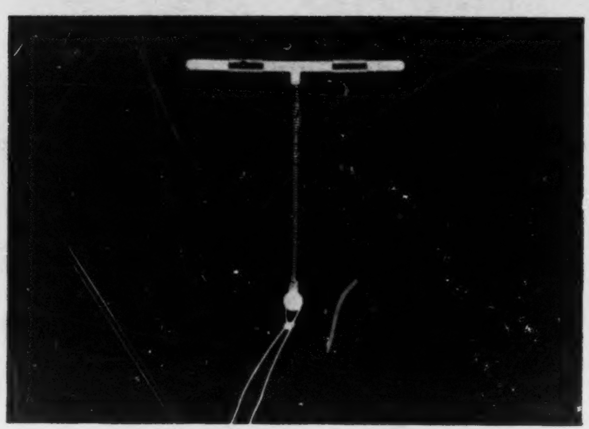


**Figure 9. TCu-380A and TCu-380Ag**

The TCu-380A carries two sleeves of solid copper on the transverse arm and a coil of copper wire around the stem. In the 380Ag, which is not yet available commercially, the copper wire has a silver core to keep the copper from fragmenting. This lengthens the effective life of the device. Total exposed copper surface area is 380 square mm.

Developer: Population Council

Date marketed: 1982

Distributors: Ortho Canada; Outokumpu Oy, Finland (investigational use only).

Length: 36 mm

Width: 32 mm

Tail: Two white threads, formerly blue.

Inserter type: Withdrawal

Inserter diameter: 4.4 mm

Effective life: TCu-38CA, developer's estimate, 6–10 years; approved in Canada, 30 months. TCu-380Ag, developer's estimate, 10–15 years.

Area of major use: Canada

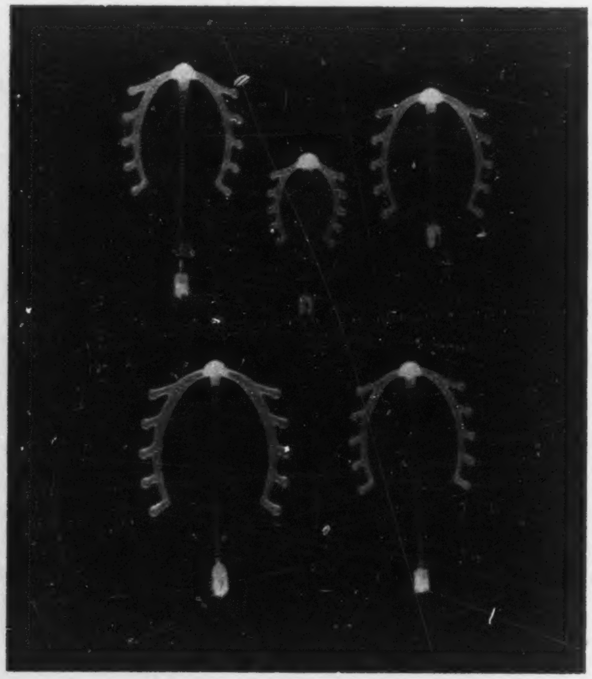


Figure 10. Multiload-cu 250 and Multiload-cu 375

Description: Copper-releasing devices with 250 square mm of copper wire around the stems of the Multiload-cu 250 models and 375 square mm on the Multiload-cu 375. The arms are flexible plastic serrated fins that help to hold the device in place. The Multiload-cu 250 comes in four sizes: the standard size, a smaller size ("Mini"), a model with standard-sized fins but a shorter vertical shaft ("Short"), and a larger size ("Maxi"). The Multiload-cu 375 (lower right) is available only in the standard size.

Developer: W. A. A. van Os

Date marketed: 1974

Distributors: Multilan S.A., Switzerland; Organon International B.V., Netherlands; G.D. Searle Ltd. of Canada; Parke Davis, Italy; Laboratoires CCD, France.

Width: Standard and Short, 16-20.5 mm; Mini, 12-13 mm; Maxi, 21-25 mm.

Tail: Two threads; Standard (250 and 375), translucent; Mini and Short, black; Maxi, blue.

Inserter type: Withdrawal (no plunger)

Width of device during insertion (fins remain outside inserter tube): Standard and Short, 12 mm; Mini, 9 mm; Maxi, 14 mm.

Effective life: Multiload-cu 250, manufacturer's recommendation, two years; Multiload-cu 375, manufacturer's recommendation, three years.

Areas of major use: Western Europe, Indonesia.

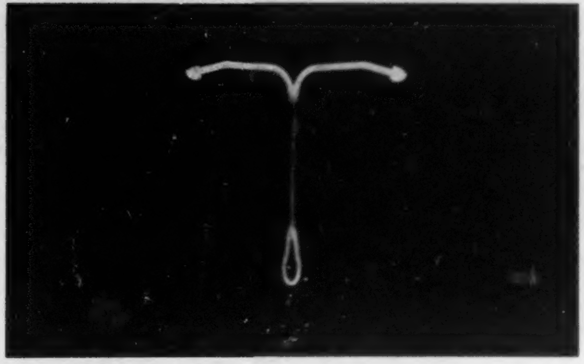


Figure 11. Nova T, or Novagard

**Description:** Injection-molded of polyethylene with barium sulfate added for radiopacity. The copper wire wrapped about the vertical stem of the device exposes 200 square mm of copper. The wire contains a silver core to extend the effective life of the device.

**Developers:** US Patent No. 3,937,212 assigned to Outokumpu Oy

**Date marketed:** 1979

**Distributors:** Huhtamaeki Oy, Leiras Pharmaceuticals, Finland; Outokumpu Oy, Finland; AB Kabi, Sweden; Schering AG, West Germany.

**Length:** 32 mm

**Width:** 32 mm

**Tail:** Two white threads

**Inserter type:** Withdrawal

**Inserter diameter:** 3.6 mm

**Effective life:** Manufacturer's estimate, at least 10 years.

**Areas of major use:** Europe, Canada, South Africa, Taiwan.

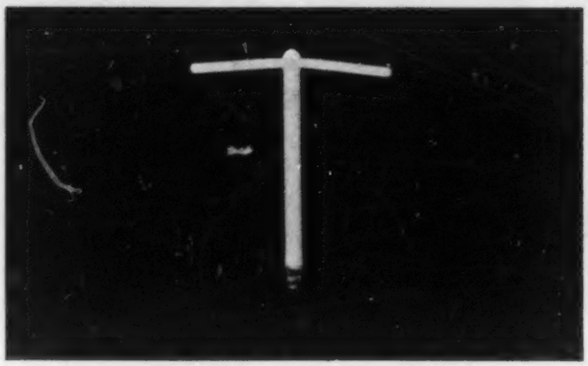


Figure 12. Progestasert Intrauterine Contraceptive System

**Description:** Uses the same T shape as the TCu-200. Progesterone in silicone oil base is released to the uterus at the rate of 65 mcg per day through the wall of the ethylene vinyl acetate copolymer stem. The reservoir in the stem contains 38 mg of progesterone. The transverse arm is solid copolymer.

**Developer:** Alza Corporation, US

**Date marketed:** 1976

**Distributors:** Alza Corporation, US; Grunenthal GMBH, West Germany; Kempthorne Medical Supplies, New Zealand; Polcrome Ltd., UK; Recordati S.A., Italy; Theraplix Division, Rhone Poulenc Santé, France.

**Length:** 36 mm

**Width:** 32 mm

**Tail:** Two black threads

**Inserter type:** Modified withdrawal, automatic loading; inserter is curved to mimic the curve of most uterine cavities but pliable to fit others.

**Width of device during insertion** (arms remain outside insertion tube): 8 mm.

**Effective life:** USFDA-approved, one year; France, 18 months.

**Areas of major use:** US, Western Europe.

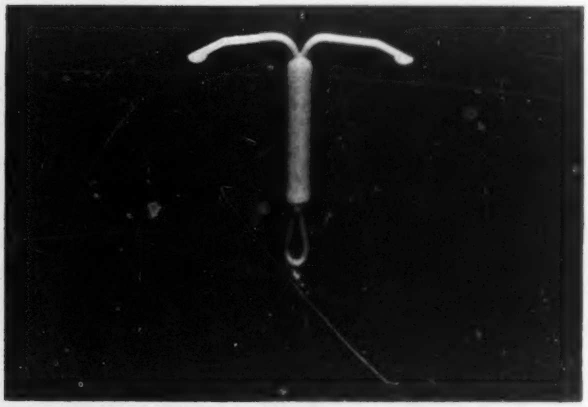


Figure 13. Levonorgestrel IUD 20

**Description:** Uses the Nova T shape, but with a capsule on the stem. The core of the capsule contains a mixture of silicone rubber and the progestin levonorgestrel. This device is undergoing clinical trials and has not yet been marketed. The model currently being tested contains 60 mg of levonorgestrel released at a rate of 20 mcg per day.

**Developer:** Steroid Research Laboratory (Finland) with Population Council

**Length:** 32 mm

**Width:** 32 mm

**Tail:** Two white threads

**Inserter type:** Withdrawal

**Inserter diameter:** 4.5 mm

**Effective life:** Developer's estimate, at least 7 years.

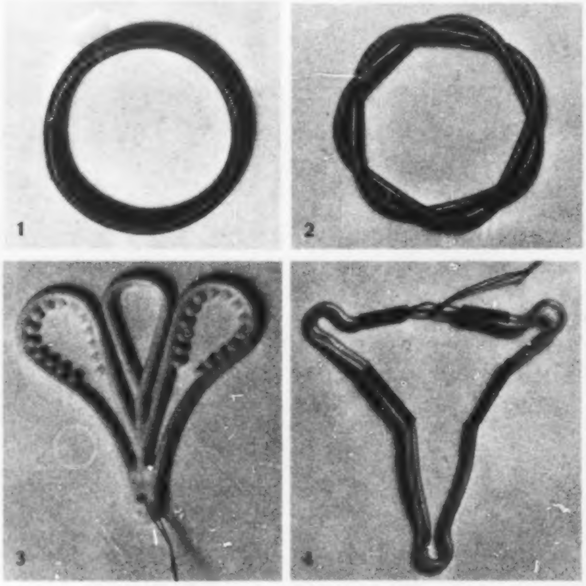


Figure 14. Chinese IUDs

The most widely used IUDs in China are 2 tailless stainless steel rings, a single ring of coiled wire (1) and the *mahua* ring (2), a double coil. Both come in many sizes. Two IUDs in regional use are the Canton Flower (3), with flexible plastic petals that move as the uterus moves, and the Shanghai Copper V200 (4), silicone plastic and 200 square mm of copper wire on a flexible wire frame.

IUD itself. WHO has been testing eight nonsteroidal antiinflammatory drugs that are taken orally. Preliminary results show an average reduction in blood loss ranging from 26 to 35 percent with three of these compounds--indomethacin, flufenamic acid, and alcofenac. These drugs offer some relief from menstrual pain as well and cause few side effects (551). Other prostaglandin synthetase inhibitors, such as naproxen, tolfenamic acid, and mefanamic acid, also alleviate dysmenorrhea and decrease blood loss (61, 90, 128, 563). Prostaglandin synthetase inhibitors may present various long-term risks, however (19).

IUDs are now being developed that release antifibrinolytic agents (205, 484). These agents—epsilon aminocaproic acid (EACA) and tranexamic acid (AMCA)—are known to be effective orally in reducing blood loss (62, 240, 330, 331). WHO is currently working on IUDs that release diamidines, drugs that may reduce both bleeding and fertility (552). As yet it is uncertain whether any of these devices can be manufactured cheaply enough for widespread use or if important improvements in performance will result.

## INFECTION

Recently new attention has focused on pelvic inflammatory disease. PID is a common health problem. In the US and northern Europe about one to two percent of women of reproductive age contract PID every year (12, 117, 253, 535). In some developing countries PID is widespread, but the exact incidence is unknown (314). PID is caused largely by sexually transmitted infections. In developing countries PID also occurs after childbirth, induced or spontaneous abortion, and genital tuberculosis.

PID in the fallopian tubes (salpingitis) can cause adhesions or complete tubal obstruction. Thus ectopic pregnancy or infertility may occur even after only one episode (177, 219, 531, 534, 535, 539). For example, in a Swedish study of 415 women with a history of salpingitis, 21 percent were infertile, compared with 3 percent in a comparison group with no history of salpingitis. Ectopic pregnancy was six times as common among the women who had had PID as among the controls (534).

IUD users, particularly young women who are exposed to sexually transmitted diseases, are more likely to develop PID than nonusers. All women who develop PID require prompt treatment with antibiotics, and those using an IUD may need to have the device removed.

The relationship between IUD use and PID is difficult to quantify for at least two reasons: imprecise criteria for diagnosis of the disease and lack of a standard reference group for comparison with IUD users (56, 93, 115, 124, 407, 424, 535). Pelvic inflammatory disease is a general term for infection of the upper genital tract including the uterus, fallopian tubes, and ovaries. Many cases are asymptomatic and difficult to diagnose, even with laparoscopy (114, 535, 552). Moreover, both oral contraceptives and barrier methods protect against PID (59, 117, 121, 346, 400, 407, 536). Thus, the estimated relative risk of PID with IUD use is higher if IUD users are compared with women using these methods rather than with women using no contraception. In addition, most studies do not take account of the number of sexual partners, the frequency of intercourse, or history of salpingitis—all important risk factors in PID. Furthermore, in some areas women most exposed to sexually transmitted diseases may have been most likely to have had IUDs inserted. These risk factors vary in different communities and are difficult to identify.

Studies in the US and Sweden find that IUD users are about 1.5 times, or 50 percent more likely to develop PID than sexually active women using no contraception at all (59, 535). In the US Women's Health Study, involving 4,900 women, current IUD users were 1.6 times as likely to be hospitalized with PID as women using no contraception and 4.5 times as likely as oral contraceptive users (59). A higher risk of PID persisted for about 12 months after the device was removed. In Lund, Sweden, from 1970 to 1974 the rate of PID in women age 20-29 was 5.2 per 100 woman-years for IUD users compared with 3.4 for sexually active women using no contraception and 0.9 for oral contraceptive users (535, 536). Other recent studies in developed countries have found the relative risk of developing PID ranges from 1.5 to 10 for IUD users compared with women using various other methods of contraception or no method (see Table 7). Despite the apparently higher risk for IUD users, in multicenter WHO studies comparing different IUDs, rates of removal for PID are low—usually less than one per 100 women after two years (551).

It is not clear whether PID in IUD users takes a more severe form than in nonusers. Formation of an abscess in the fallopian tubes or ovaries is one of the most severe forms of pelvic infection. Many of the reported cases of tubo-ovarian abscesses have involved IUD users (91, 105, 138, 141, 142, 226, 281, 318, 421, 485). While most tubo-ovarian abscesses are bilateral, several studies have found that IUD users were more likely to have unilateral abscesses (138, 141, 573). Other studies report no difference (105, 117, 421).

Whether PID is more likely to occur with longer IUD use is also unclear, since studies report conflicting results (59, 224, 527). Unpublished data from the Contraceptive Evaluation Branch of the US National Institutes of Health suggest that women using IUDs for five or more years may experience more severe but not more frequent episodes of PID (462).

In developed countries PID in IUD users, as in nonusers, occurs most frequently among women under age 25 (49, 59, 121, 286, 342, 345, 551, 552). For example, among 871 nulliparous British women fitted with the Cu-7, the life table rates for PID after 30 months of use were 14.2 for women age 16 to 19 and 1.2 for women age 30 to 49 (49). Younger women may have more sexual partners than older women and thus be more exposed to sexually transmitted diseases (49, 59, 114).

Studies on the role of parity are inconclusive. Some researchers have found that the rate of PID is higher in IUD users who have never been pregnant or borne children than in other women (117, 348, 535, 5[illegible]0). Others find no difference (59, 253, 286, 345, 346).

### Mechanisms of Infection

PID develops when microorganisms from the lower genital tract ascend into the uterus and fallopian tubes. Several physiological factors have been suggested as accounting for the association between IUDs and PID:

- sterile inflammatory reaction in the fallopian tubes and the endometrium,
- increased volume and duration of menstrual bleeding,

- ascent of bacteria along the IUD tail,
- introduction of bacteria into the uterus during insertion.

Since 1976 six studies of women undergoing sterilization in developed and developing countries have shown that chronic, nonbacterial inflammation of the tubes is more common in IUD users than in nonusers (34, 115, 292, 364, 443, 552). This inflammation may reduce resistance to the growth of pathogenic organisms (115, 443). Also, IUDs can cause small ulcerations in the endometrial wall that could allow bacteria to enter underlying tissue, thus increasing the risk of infection (312).

Increased bleeding associated with IUD use may also enhance bacterial growth (184, 474, 557). Bacteria are more likely to enter the endometrium during menstruation, when the cervical mucus plug is absent, and most species of bacteria multiply rapidly in the presence of blood (113). PID, particularly gonococcal infection, occurs more often just after menses than at other times in the menstrual cycle (117, 119, 184, 196, 297, 557).

The tail of the IUD is a potential route of infection. Cervical bacteria can ascend into the uterus along the tail of the IUD. In Britain, Richard Sparks and colleagues studied women undergoing hysterectomy. They found bacteria in the uterine cavities of 12 of 14 women using IUDs with monofilament tails and in all three women using Dalkon Shields with multifilament tails. There were no bacteria in the uterine cavities of five women who had used tailless Dalkon Shields or of 50 nonusers (457, 458). Other studies suggest that multifilament tails more readily

### Table 7. Pelvic Inflammatory Disease (PID) and IUDs, Selected Recent Studies, 1979–1981

| Author, Date, & Ref. No. | Place | Study Design | Description of Participants | Findings |
|---|---|---|---|---|
| **Burkman & Women's Health Study 1981** (57, 59, 341) | US | Multicenter case-control | 1,447 cases hospitalized with PID; 3,453 controls | —Relative risk for IUD users was 1.6 times higher than for noncontraceptors; 4.5 times higher than for pill users; 3.3 times higher than for users of barrier methods.<br>—Risk higher for Dalkon Shield, lower for Cu-7 and Lippes Loop. |
| **Flesh et al. 1979** (124) | US | Case-control | 163 cases hospitalized with acute salpingitis; 222 controls | —Significantly more cases (25%) than controls (14%) were IUD users. (Unadjusted relative risk = 2.1)<br>—Ethnic group, number of sexual partners, and history of salpingitis affected risk. |
| **Kaufman et al. 1980** (224) | Canada, Israel, US | Multicenter case-control | 44 cases hospitalized with PID; 259 controls | —Age-adjusted relative risk for all IUD users: 6.5; for IUD use ≥5 years = 12.9; for <5 years = 5.7.<br>—Relative risk by device: Cu-7 = 3.8; Lippes Loop = 7.9; Saf-T-Coil = 9.2; Dalkon Shield = 12.3. |
| **Larsson et al. 1981** (253) | Sweden | Cohort | 996 IUD users; 176 nonusers | —No evidence that copper IUDs increased the risk of PID in all users, in users with a history of PID, or in long-term users. |
| **Osser et al. 1980** (346) | Sweden | Case-control | 690 cases hospitalized with acute salpingitis; 690 controls | —Relative risk for current IUD users = 2.1.<br>—No significant difference in frequency of PID between ever- and never-pregnant users. |
| **Paavonen & Vesterinen 1980** (348) | Finland | Case-control | 144 cases hospitalized with acute salpingitis; 229 controls | —Significantly more cases (58%) than controls (31%) were IUD users. (Unadjusted relative risk = 3.0)<br>—Relative risk for IUD users was 2 times higher than for women using no contraception or a method other than the pill. |
| **Ryden et al. 1979** (407) | Sweden | Cohort | 672 women with gonorrhea; 85 used IUDs, 342 used hormonal methods, 245 used neither | —24% of IUD users had PID complicating the gonorrhea, compared with 9% of users of hormonal methods and 15% of those using neither IUDs nor orals. Difference between women using IUDs for more than 3 weeks and those using neither IUD nor orals is not statistically significant. |
| **Vessey et al. 1981** (527) | UK | Cohort | 17,032 women; woman-years of observation: users = 20,482, ex-users = 4,210, nonusers = 65,259. (101 developed PID) | —Incidence of PID per 1,000 woman-years:<br>Diagnosis — Current IUD Users / Ex-IUD Users / Users of OCs & Barriers<br>Acute definite — 1.51* / 0.48 / 0.14<br>Chronic definite — 0.54* / 0.95* / 0.23<br>Other — 0.54 / 0.48 / 0.25<br>*Significantly different from rate for OC and barrier users ($p < 0.05$) |
| **Westrom 1980** (535) | Sweden | Cohort | All women age 20–29 in Lund, Sweden, 1970–74 (571 developed PID) | —Incidence of PID per 1,000 woman-years of method use:<br>All IUD users 52<br>Never-pregnant 118<br>Ever-pregnant 34<br>OC users 9<br>Barrier method users 14<br>Sexually active, no method 34<br>Sexually inactive, no method 0 |

Note: Earlier studies are reported in **Population Reports**, *IUDs—Update on Safety, Effectiveness, and Research*, B-3, May 1979, Table 15, p. B-68.

permit bacteria to ascend than monofilament tails (440, 481, 482, 483). One hypothesis is that the sheath of the Dalkon Shield tail may deteriorate during use. This would expose the inner filaments, which are made of highly absorbent nylon, providing a suitable surface for bacterial growth (291).

In several studies the Dalkon Shield, which is no longer on the market, has been linked with an increased risk of inflammation or PID (34, 105, 124, 141, 485, 527), although other researchers have found no difference among types of IUDs (115, 117, 142). Preliminary unpublished data from the US Women's Health study suggest that long-term Dalkon Shield users are at least five times more likely to be hospitalized for a first episode of PID than long-term users of other devices (57, 341). Whether the multifilament tail or other features of the device are involved is not clear.

Of the IUDs currently on the market or being studied, no significant difference has been found in PID rates. These studies involve unmedicated and copper devices, including the Lippes Loop, Saf-T-Coil, Cu-7, and TCu-200 (59, 124, 253, 527, 536, 551). It is possible that progestin-releasing devices cause fewer inflammatory changes or infections than other devices. In one study of 113 women undergoing sterilization, none of the 13 women using the Progestasert showed any signs of inflammation or infection; approximately half of those using various unmedicated and copper devices had nonbacterial inflammation and about half had normal tubes (115). In Finland, with levonorgestrel IUDs Tapani Luukkainen and Carl Nilsson report only three removals for infection in over 15,000 woman-months of use (284). The infection rate may be low because levonorgestrel reduces both the volume and total days of menstrual bleeding. Also, levonorgestrel causes thickening of the cervical mucus, which could prevent bacteria from entering the uterus (283). Larger, comparative studies would be necessary to confirm these findings.

### Prevention

So far, research on ways to prevent pelvic infection among IUD users has been extremely limited. In addition to clinical guidelines that might limit IUD use to women at low risk of developing PID, two approaches have been considered:

- better sterilization and insertion techniques,
- modified devices either without tails or releasing substances that minimize infection.

Better sterilization and insertion techniques might be useful because bacteria from the cervix and vagina are introduced into the uterus when an IUD is inserted (59, 115, 338, 345, 346, 497). Currently, IFRP is sponsoring studies on different chemical disinfectants for sterilizing IUDs (see p. B-128), and research is continuing on IUD strings that release an antiseptic into the cervical canal (255). These measures cannot eliminate all infection, however, since many women develop PID months after insertion (117, 121, 253, 286, 348).

Modified devices, including devices without tails, might reduce the incidence of infection. So far, however, only one (111) of five small studies comparing devices with and without tails has found a lower rate of infection in women with tailless devices (53, 111, 210, 262, 546). Moreover, there would be other problems. With tailless IUDs, women would not be able to check whether the device was in place, and health personnel would have difficulty removing it in case of pregnancy. Thus substantial redesign might be necessary.

Other modifications are possible, including devices that release various progestins, antibiotics or other substances (589). Most changes in IUD design involve tradeoffs, however. For example, IUDs releasing synthetic progestins reduce the volume of bleeding and possibly PID but may increase other complications such as ectopic pregnancy or systemic side effects.

### Treatment

Prompt recognition and treatment of PID may reduce tubal damage and subsequent problems such as infertility and ectopic pregnancy (100). PID is sometimes difficult to diagnose, however (114, 213, 535). Common symptoms include any or all of the following: abdominal pain, adnexal tenderness, pain with cervical manipulation, fever, and discharge from the vagina and cervix. Some women have only mild symptoms. Others may be entirely asymptomatic (535).

PID involves a number of different organisms (73, 114), which vary in different communities (7). Thus, unless tests can be carried out to identify the specific organism, a broad-spectrum antibiotic is necessary (see box, p. B-124). Gonorrhea frequently causes PID, but among IUD users nongonococcal PID is also common (117, 253, 346, 348). Nongonococcal PID is often caused by *Chlamydia trachomatis* and mycoplasmas (7, 114, 155). In Sweden and the US the most common aerobic (oxygen-requiring) organisms found in PID are *Escherichia coli, Proteus, Staphylococcus epidermidis,* and *Hameophilus influenzae.* Commonly observed anaerobes (which develop in the absence of oxygen) include *Bacteroides, Clostridium, Peptococcus,* and *Peptostreptococcus* (155). In both IUD users and nonusers, the first episode of PID is often caused by a sexually transmitted infection or by complications of induced abortion or childbirth. After one episode of PID, the fallopian tubes seem to be more vulnerable to reinfection. Thus, succeeding episodes are more often caused by anaerobic organisms normally found in the genital tract (114, 153, 535).

Some US and European physicians recommend that, once PID has been diagnosed in an IUD user, the device should be removed immediately and antibiotics should be administered (100, 142, 187, 403, 463). Others recommend that the device be removed only if the woman does not respond quickly to antibiotics (305, 452, 511, 512). A randomized Swedish study compared the two treatment methods and found that removal of the IUD did not significantly influence the rate of recovery from acute PID (452). A recent medical policy statement from the International Planned Parenthood Federation (IPPF) recommends removal of the IUD if improvement does not occur within 48 hours after the start of antibiotic treatment (211).

### Actinomyces

Recently attention has focused on a particular anaerobic organism—actinomyces—which can cause the serious but very rare pelvic infection known as actinomycosis. Actinomyces organisms, which are difficult to identify and culture (41, 71, 218, 282, 299), have sometimes been found on the cervical smears of IUD users but rarely on the smears of nonusers (24, 48, 94, 101, 130, 175, 472, 513). A recent study suggests, however, that actinomyces organisms normally inhabit the genital tracts of many women who do not use IUDs. Using a sensitive detection technique, researchers examined 50 women and found that actinomyces were present in 44 percent of the women with IUDs and in 27 percent of those without (85). The presence in the genital tract of organisms resembling actinomyces does not necessarily indicate infection. The majority of women with such organisms are asymptomatic (24, 130, 175, 176, 218, 472), and reported cases are few (155, 478).

23

Whether the presence of actinomyces in the genital tract of IUD users, without other signs or symptoms of infection, requires treatment has not yet been resolved. Some clinicians believe that IUDs should be removed if actinomyces-like organisms are seen on cervical smears and then reinserted only after negative cervical smears have been obtained (31, 48, 89, 169, 289, 461, 513). Others suggest that IUDs should not be removed from asymptomatic women but that these women should be closely watched for signs of infection (1, 24, 472). Women with actinomyces-like organisms often remain asymptomatic after many months of continued IUD use (24, 85, 221). All agree, however, that when pelvic tenderness or other symptoms of infection are present, the IUD should be removed, and antibiotics effective against actinomyces organisms—penicillin and tetracycline (31, 155, 289, 442)—should be administered (24, 31, 175, 289). Adnexal masses usually require surgery (1, 442).

To minimize the possibility of infection from actinomyces-like organisms, some researchers have gone so far as to recommended routine removal and reinsertion of all IUDs every three years (54, 387, 391, 416). Since the likelihood of harboring these organisms increases with the length of IUD use (24, 48, 101, 176, 353, 391, 416), it is assumed that removal would disrupt bacterial growth.

The prevailing view, however, opposes routine removal and reinsertion (120, 186, 211, 352, 453). For example, routine removal is opposed by the medical advisory panel of the UK Family Planning Association and the National Association of Family Planning Doctors of Great Britain (120), by the Obstetrics-Gynecology Device Section of the Obstetrics-Gynecology and Radiologic Device Panel of the US Food and Drug Administration Advisory Committee (512), by the National Medical Committee of the Planned Parenthood Federation of America (583), and by the International Medical Advisory Panel of IPPF (211). Moreover, since the risk of PID, perforation, and other complications is highest in the first few months after insertion, reinsertion may increase rather than remove PID risk (1, 186). In a 1981 statement on IUDs, the IPPF panel concluded:

> . . . clinical infection with actinomycosis is a very small component of the total spectrum of pelvic inflammatory disease associated with IUDs, and the existence of a relationship between duration of use of an IUD and development of actinomycosis infection is not conclusive. Current data therefore provide no support for the suggestion that inert devices such as the Lippes Loop should be replaced at regular intervals in those women who are free from significant side-effects. (211)

## Antibiotic Therapy For PID

What is the best antibiotic for treating PID? There are no reliable clinical signs to distinguish gonococcal from nongonococcal PID. Thus, when laboratory facilities for identifying specific causative organisms are not available, an antibiotic effective against a wide range of pathogens is necessary. For mild to moderate cases of unspecified PID, a recent WHO report on sexually transmitted diseases recommends tetracycline. The dosage should be 500 mg taken orally, four times a day, for 10 days (548). Severe cases of PID with pelvic abscesses and, at times, peritonitis, usually involve anaerobic organisms (35). Recommended antibiotics include tetracycline, metronidazole, clindamycin, kanamycin, or gentamicin, usually given intravenously (10, 35, 381, 470, 537).

For treatment of gonococcal PID on an outpatient basis, the US Centers for Disease Control (CDC) suggest tetracycline 500 mg taken orally, four times a day, for 10 days, in addition to either 500 mg ampicillin or 500 mg amoxicillin, taken on the same regimen (508). For hospitalized patients penicillin G, tetracycline, amoxicillin, or metronidazole are recommended (10, 508, 381). Pregnant women should not take tetracycline. Other antibiotics, including procaine penicillin, ampicillin, and amoxycillin, can be safely used (508).

In all cases, the woman's sexual partner should also be treated with antibiotics to prevent reinfection and recurrence of PID.

## PREGNANCY

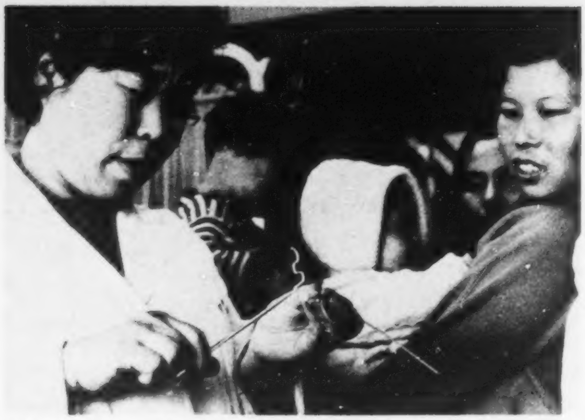
The IUD is one of the most effective contraceptive methods. Pregnancy rates range from less than one to about five per 100 women per year (see p. B-103). If a pregnancy does occur with an IUD in place, however, complications may result, and medical attention is required. Early removal of the IUD will improve a woman's chances of safe pregnancy and delivery, but even after removal the risk of spontaneous abortion will still be higher than for a nonuser. A pregnancy in an IUD user is more likely to be ectopic than a pregnancy in a nonuser, but whether IUDs actually increase the risk of ectopic pregnancy or simply fail to prevent as effectively as they prevent uterine pregnancy it is not clear.

### Uterine Pregnancies

If pregnancy occurs with an IUD in place, that pregnancy is more likely to end in a spontaneous first or second trimester abortion than pregnancy in a nonuser. About 50 percent of uterine pregnancies spontaneously abort if the device is not removed (16, 201, 235, 430, 450, 465, 480, 523, 524, 528). This is about three to five times the rate of spontaneous abortion for other women (201, 232, 523). In some studies over half of the spontaneous abortions in IUD users occurred in the second trimester of pregnancy (269, 465). A recent US case-control study of 539 cases found that pregnant women with an IUD in place were 26 times as likely as women without an IUD to experience a *septic* second trimester spontaneous abortion (126). Complications of any second trimester abortion are usually more serious than those of an early abortion.

Removing the IUD early in pregnancy cuts the excess risk of spontaneous abortion at least in half (16, 450, 480) and, according to one study, eliminates any excess risk of second trimester abortion. In a US study the relative risk of nonseptic second trimester spontaneous abortion for IUD users compared with nonusers dropped from 10.3 to 1.5 if the IUD was removed, and the risk of septic spontaneous abortion, from 26.4 to 1.2 (126).

The risk of septic second trimester abortions with IUDs first became apparent in the early 1970s. From 1972 through 1974 there were 50 reported deaths in the US associated with first and second trimester spontaneous abortion; 17 of these women were IUD users (69). One device, the Dalkon Shield, posed three times the risks of other devices (69). In 1974 the A. H. Robins Company, manufacturers of the Dalkon Shield,



A South Korean family planning worker demonstrates a Lippes Loop and inserter. In Korea 20 percent of contraceptors use IUDs. (USAID)

withdrew the device from the market. The US Food and Drug Administration and the Robins Company instructed doctors to remove any type of IUD from women who became pregnant (5, 388). Since 1974 only two US women using IUDs have died from septic spontaneous abortion (67, 68). IPPF recommends that all women still using Dalkon Shields should have these devices removed even if they are not pregnant (211). Recent reports of higher PID rates among women who used Dalkon Shields reinforce this recommendation (see p. B-123).

An IUD cannot be easily removed from a pregnant woman when the strings are not visible. Probing the uterus to locate the strings or to remove a tailless device may disrupt the pregnancy. In this case, the IUD must be left in place if the woman wants to continue the pregnancy (106, 233). Close supervision is essential, since sepsis may develop rapidly, with only mild early symptoms (69, 75). When sepsis is suspected, antibiotic therapy and immediate uterine evacuation are mandatory (106, 504) (see **Population Reports**, *Complications of Abortion in Developing Countries*, F-7, July 1980).

Not only spontaneous abortion but also premature delivery, stillbirth, and lower birth weights are more common if an IUD is left in place during pregnancy (16, 480, 524). For example, the Oxford University/Family Planning Association (Oxford/FPA) cohort study found that 14 percent of infants of women who became pregnant with an IUD in place weighed less than 2,500 grams, compared with 9 percent of infants of women using oral contraceptives and 2.4 percent of infants whose mothers used other methods (524). This difference was highly statistically significant. There is no evidence, however, that IUDs cause birth defects, even if the device remains in place (106, 233, 306, 351, 363, 450, 524). Also, there is no evidence that past use of an IUD leads to complications during a subsequent uterine pregnancy (126, 524).

### Ectopic Pregnancies

A link between ectopic pregnancy—the implantation of a fertilized ovum outside the uterus—and IUDs has been recognized since 1929 (263). The link is still not completely understood, however.

One point is clear. When an IUD user becomes pregnant, the pregnancy is more likely to be ectopic than pregnancy in a nonuser. It has been estimated that in IUD users about one in 30 pregnancies, or 3 to 4 percent, is ectopic. In other women, about one in 125 pregnancies, or 0.8 percent, is ectopic (32, 55, 306, 351, 437, 438). (See **Population Reports**, *IUDs—Update on Safety, Effectiveness, and Research*, B-3, May 1979). One explanation for this difference, first offered in 1970 by Hans Lehfeldt and Christopher Tietze, is that IUDs provide more protection against uterine pregnancies than against tubal or other extrauterine pregnancies (263).

More recently, it has also been suggested that IUDs may increase the risk of ectopic pregnancy by affecting the fallopian tubes. Epidemiologic evidence for this hypothesis comes from studies showing increasing rates of ectopic pregnancy with longer IUD use (343, 435, 479). For example, in the US Women's Health Study, involving over 4,000 women, IUD users with no history of ectopic pregnancy or PID who had used IUDs for 25 months or more had 2.6 times greater risk of ectopic pregnancy than women who had used IUDs for less than 25 months. The risk persisted for one year after the IUD was removed. Researchers suggest that a duration-of-use effect could be caused by the gradual development of nonbacterial inflammatory changes in the tubes (343) (see p. B-122). In US studies of various copper T devices, the chance of ectopic pregnancy in the first and second years of use was 1.1 per 1,000 women; in the third and fourth years, 2.6 per 1,000 (435). By contrast, no duration-of-use effect was found in the Oxford/FPA study, and the rate of ectopic pregnancies in IUD users remained fairly constant at 1.2 per 1,000 women per year (526).

Other epidemiologic evidence does not make clear whether IUDs actively increase the risk of ectopic pregnancy. In the Women's Health Study, even though long-term IUD users faced greater risk than short-term users, the risk of having an ectopic pregnancy was no higher for long-term users than for women who had never used IUDs. This suggests that the IUD has a possible protective effect at first, which wears off with time (343). Ectopic pregnancy rates among US women using IUDs in Population Council studies were not clearly different from estimated national rates of ectopic pregnancy among all US women not using IUDs or oral contraceptives or sterilization (435).

Comparisons of ectopic pregnancy rates in IUD users and other women (435, 522, 539) are difficult to interpret because a satisfactory control group is hard to find. Oral contraceptives virtually eliminate all risk of ectopic pregnancy, since they prevent ovulation. Barrier methods of contraception may also have a protective effect (343). Also, ectopic pregnancy rates vary widely in different populations depending on such factors as previous ectopic pregnancy, prevalence of pelvic infection, and age (127, 193, 219, 268, 343, 401, 414, 417, 466, 479). IUD users have higher rates of PID, however, and a history of PID is known to increase the risk of ectopic pregnancy (see p. B-121). For example, in Lund, Sweden, rates of ectopic pregnancy were four to six times higher in women with a history of PID than in women with no history of PID (539).

While the physiological and epidemiological evidence on ectopic pregnancy and IUDs is still inconclusive, the clinical significance is clear:

- If an IUD user conceives, the possibility of an ectopic pregnancy must always be considered.
- All women using IUDs should know the symptoms of ectopic pregnancy—abdominal pain, dark and scanty vaginal bleeding, or amenorrhea—and the importance of getting prompt medical attention.
- Women already at high risk of an ectopic pregnancy—due to previous PID, ectopic pregnancy, or tubal surgery—should not use IUDs if other methods are feasible.

## Table 8. Rates of Ectopic Pregnancy Among IUD Users, by Type of IUD, Selected Studies, 1970–1981

| Author & Date | Ref. No. | Type of IUD | Woman-Years of Use | Ectopic Pregnancies per 1,000 Woman-Years |
|---|---|---|---|---|
| POOLED DATA | | | | |
| **Gibor & Pharris 1980** | 137 | Progestasert | 9,802 | 5.4 |
| **Sivin 1979** | 435 | Copper IUDs | 21,875 | 0.96 |
| **Snowden 1977** | 448 | Lippes Loop | 5,000 | 0.6 |
| | | Cu-7 & TCu-200 | 4,000 | 0.5 |
| **Tietze & Lewit 1970** | 497 | Various unmedicated IUDs | 28,614 | 1.2 |
| **USFDA 1979** | 510 | TCu-200 | 11,036 | 0.5 |
| | | Cu-7 | 13,135 | 0.4 |
| | | Progestasert | 10,567 | 4.0 |
| **Vessey et al. 1979** | 526 | Lippes Loop | 9,834 | 1.2 |
| | | Saf-T-Coil | 4,712 | 0.8 |
| | | Copper IUDs | 739 | 1.4 |
| | | Others & unknown | 2,010 | 2.0 |
| COMPARATIVE STUDIES | | | | |
| **Alza 1982** | 17 | Progestasert | 417 | 2.4(1*) |
| | | Plastic T | 365 | 2.7(1*) |
| **Diaz et al. 1980** | 95 | 5 steroid-releasing Ts | 433 | 11.5(5*) |
| | | TCu-200 | 93 | 0.0 |
| | | Plastic T | 49 | 0.0 |
| **Fylling & Fagerhol 1979** | 131 | Progestasert | 144 | 13.9(2*) |
| | | Nova T | 124 | 0.0 |
| **Larsen et al. 1981** | 244 | Progestasert | 166 | 6.0(1*) |
| | | TCu-200 | 162 | 0.0 |
| **Pizarro et al. 1977** | 362 | Progestasert | 131 | 0.0 |
| | | Cu-7 | 130 | 0.0 |
| **WHO 1979** | 554 | Progestasert | 282 | 0.0 |
| | | Plastic T | 246 | 4.0(1*) |

*Number of ectopic pregnancies

### Differences Among Devices

Ectopic pregnancy rates may be higher with progestin-releasing IUDs than with other types (see Table 8). Pooled clinical trials of the Progestasert show a rate of about 5 ectopic pregnancies per 1,000 woman-years (17, 137). By contrast, the rate for unmedicated devices reported by the Population Council Cooperative Statistical Program is 1.2 (497). For copper devices, Population Council studies show a cumulative rate of 0.96 (435). Comparisons such as this, involving different studies with different populations, may be unreliable, however, since risk factors for ectopic pregnancy vary widely (26, 37, 133, 355, 358). Comparative trials have found that the Progestasert had a higher ectopic pregnancy rate than the Nova T (131) and the TCu-200 (244), but the same rate as the Cu-7 (362). There was no difference between the Progestasert and its plastic component without progesterone (17, 554). A small comparative trial found a higher ectopic pregnancy rate with various experimental progestin-releasing IUDs than with the TCu-200 or an unmedicated plastic T (95). A greater risk of ectopic pregnancy with progestin-releasing IUDs is plausible, since another progestin contraceptive, the mini-pill, has shown higher than expected ectopic pregnancy rates (38, 45, 278, 444).

### Subsequent Fertility

The effect of IUD use on subsequent fertility has not been fully evaluated, since most studies involve only IUD users who discontinue the method in order to become pregnant (106, 185, 504). Among these women the return to fertility is rapid, and generally over 70 percent conceive within 12 months after IUD removal (33, 50, 95, 215, 225, 230, 325, 422, 438, 497). The Oxford/FPA study found that some women were slow to recover their fertility, but within two years after discontinuation 92 percent of 258 women had given birth (525).

Only one study, involving over 2,500 users of the Lippes Loop in Taiwan, has followed women whose devices were removed for medical as well as personal reasons. Based on estimates of average fecundability and taking account of subsequent contraception, the analysis suggests that, among women over age 30, the likelihood of conception declined with duration of IUD use. Although no clinical evidence was available, the researchers hypothesized that decreased fecundability among these former IUD users might have been due to higher rates of PID (215).

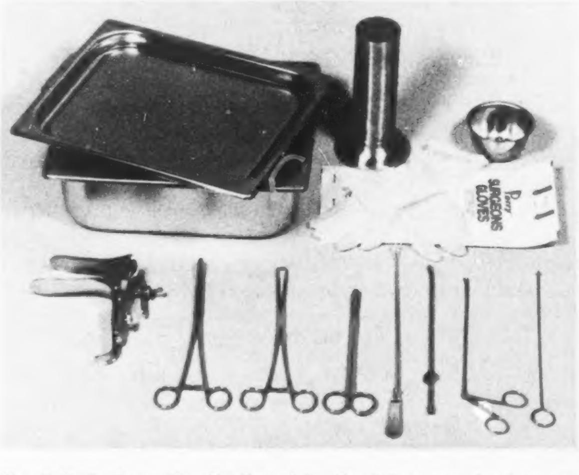
## PRODUCT AND PACKAGING ISSUES

Much IUD research has focused on clinical issues such as bleeding, pregnancy, and infection. The results have been widely reported in medical and scientific journals. Programmatic issues relating to manufacture and distribution of IUDs have so far been the special concern of a small number of agencies and firms sponsoring product development, commercial sales, or public sector distribution. Little information is published or available to the public on such important programmatic issues as:

- manufacturing capabilities in developing countries,
- comparative prices of different devices,
- the merits of bulk versus individual packaging of IUDs,
- methods of sterilizing IUDs,
- shelf life of IUDs.

### Manufacturing in Developing Countries

IUDs and inserters are currently produced in several developing countries, including China, India, and Mexico. Lippes



**The IUD Back-up Kit, distributed by the US Agency for International Development (USAID), contains all the back-up equipment needed for insertion of IUDs and follow-up of users. Each kit contains (top row, from left) one pan with five covers, one forceps jar, five iodine cups, two dozen sterile disposable surgeon's gloves, (bottom row, from left) one speculum, one sponge forceps, five uterine tenaculum forceps, one scissors, five graduated uterine sounds, one endometrial biopsy curette (for retrieving lost tails), one IUD removal forceps, and one IUD removal hook.** (USAID)

Loops have been manufactured in India throughout most of the last decade. Copper T devices are being produced in Mexico and are slated for production in Brazil, China, India, and Indonesia (52).

IUD production can range from assembly and packaging of components purchased from other manufacturers to full-scale plastic molding, production of all components, assembly, packaging, and sterilization (129, 575). The technology of IUD production is unique among contraceptive technologies in that it is available from both the private and public sectors, allowing a variety of technology transfer arrangements (575).

The decision about which components are produced locally and which are imported depends upon local capabilities on one hand and barriers to imports on the other. The best strategy for starting IUD production may be to begin with assembly and packaging operations and build up. For developing countries with sufficient demand for IUDs, it may be most feasible to make the plastic body of the IUD and the plastic inserter and flange in a local factory while the IUD tail and copper and packaging components are imported (129). Local contractors may be able to carry out blending of the plastic materials, mold repair, quality-control analyses, and, sometimes, plastic injection molding and gas sterilization of individually packaged devices.

The cost of setting up production of sterilized, individually packaged copper IUDs (such as the TCu-220C or TCu-380Ag) in a developing country is estimated at $2-3 million (US). The costs of actually producing IUDs in a developing country are more variable. Salaries and wages; tariffs, duties, and taxes on imported materials; availability of local energy sources; and taxes all may have significant effects on production costs. According to an overview prepared by the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), efficient operation requires production of at least one million IUDs per year. If the facility is also manufacturing other products, however, it may efficiently produce fewer IUDs, since the other products will absorb some of the fixed costs (575).

Quality control in the manufacturing process can be a serious problem. Where inadequate materials, incomplete blending of plastic, or poor manufacturing techniques are used, the IUDs may be of inferior quality—for example, too brittle—which could injure the user and jeopardize the reputation of a family planning program. This has occurred in some countries where small-scale operations have produced IUDs illegally (52). Current efforts to establish IUD manufacturing are concentrated on large countries with the appropriate labor force and, in some cases, governments committed to assisting the fledgling enterprise.

### Prices

IUD prices vary greatly. Manufacturer's prices range from $0.12 (US) each for bulk-packaged, nonsterile Lippes Loops purchased by public sector programs to $20-$27 for an individually packaged, sterile TCu-200 or Cu-7 purchased by a commercial distributor (see Table 9). For the individual woman, an IUD may be obtainable free of charge through a family planning program or may cost as much as $50-$100 from a private physician (333). Prices of the devices are influenced by such factors as:

- raw material and production costs,
- licensing agreements,
- public or private sector sales,
- quantity purchased,
- local requirements, duties, regulations, and patents.

**Table 9. Commercial Wholesale and Public Sector Prices of IUDs Charged by Selected Distributors, 1982**

| Device | Distributor | Price (in US$) | |
|---|---|---|---|
| | | Commercial Wholesale | Public Sector |
| **Lippes Loop D** | Finishing Enterprises, US | | $0.12-$0.22 depending on order size. Bulk packaging only. |
| | Ortho, US | $90.00 box of 6. Individual sterile packages. | $47.82 box of 6 in US. Price to USAID: $37.50 for unsterilized package of 100 with 10 reusable inserters. |
| **TCu-200** | Finishing Enterprises, US | | $0.85-$1.55 depending on order size. Price to USAID and UNFPA for large orders under annual contracts: $0.81. Individual sterile packages. |
| | Searle, US | $20-$27 each. Individual sterile packages. | |
| **TCu-220C** | Promotora e Importadora PEISA, Mexico | | Individual sterile pack with inserter: $1.80 Bulk-packed: $1.08; Inserter: $.10. Orders larger than 10,000 units: prices negotiable. |
| **T modified 220 Cu** | Biotec Laboratories, Mexico | About $4.32; depends on quantity. Individual sterile packages. | About $1.30; depends on quantity. Individual sterile packages. |
| **TCu-380A** | Ortho, Canada | $16 each. Individual sterile packages. | |
| **Cu-7** | Searle, Canada | $12-14 each. Individual sterile packages. | |
| | Searle, US | $20-$27 each. Individual sterile packages. | |
| **Multiload-cu 250** | Multilan, Switzerland | Prices determined by local distributor. Individual sterile packages. | Prices depend on size of order and local conditions. 1981 price to WHO: $2.32 each. Individual sterile packages. |
| **Nova T** | Outokumpu Oy, Finland | Prices depend on quantity and local conditions. Individual sterile packages. | Prices depend on quantity and local conditions. 1981 price to WHO: about $2 each. Individual sterile packages. |
| **Progestasert** | Alza, US | $12.90-$15.80; depends on quantity. Individual sterile packages. | $8.40. Individual sterile packages. |

Note: Individual sterile package includes inserter.

Sources: Data from distributors: Alza Corporation (529), Biotec Laboratories (402), Finishing Enterprises (264), Multilan S.A. (500), Ortho Canada (576), Ortho Pharmaceutical (340), Outokumpu Oy (580), Promotora e Importadora PEISA (92), Searle Canada (587), Searle Pharmaceuticals (432); data from purchasers: WHO (320).

Raw materials cost far less than production. In the US the plastic content is usually no more than $0.003 per device. Altogether the nonmetallic materials, including threads and barium sulfate to make the device radiopaque, cost about $0.008. The seven copper sleeves used for a TCu-220C cost about $0.15, since they require special manufacture (574). How much manufacturing and packaging add to the cost depends on the amount of individual handling required. For example, TCu-200s normally cost more than Lippes Loops (see Table 9) because more labor is involved in winding the copper wire onto the device, providing individual inserters, and assembling the device and inserter (264).

Licensing agreements also can affect price. The Population Council, for example, in negotiating agreements for manufacture and distribution of the IUDs it has developed, requires that public sector prices to developing countries remain low. As a result, public sector prices are sometimes very much less than private sector prices. For example, for a sterile, singly packed TCu-200 the public sector price can be as low as $0.81, while the wholesale commercial price is $20 to $27. For a Progestasert, developed and produced by the Alza Corporation, the public sector price is $8.40, while the wholesale commercial price is between $12.90 and $15.80 (see Table 9).

In the public sector, price depends to some extent on the size of the order. By contrast, in the commercial sector, import duties, regulations, distributor's mark-up, patents, and promotional expenses influence the final price. In general, the marketing situation in each country, including the extent of competition, strongly influences the final price.

### Bulk and Individual Packaging

IUDs could theoretically be packaged in three different ways: bulk nonsterile packages, individual sterile packages, and bulk sterile packages. Lippes Loops distributed by Ortho Pharmaceutical Corporation and TCu-220Cs distributed by Promotadora e Importadora PEISA, a Mexican firm, are available in either bulk nonsterile packages or in individual sterile packages. Finishing Enterprises, a US firm, produces Lippes Loops only in bulk, nonsterile packs. All other IUDs are available only in individual sterile pack. No IUDs are currently distributed in bulk sterile packs.

Three considerations affect choice of packaging: safety, cost, and convenience. Conventional medical practice dictates that IUDs should be sterile before insertion, just as sterile technique is normally used with any pelvic procedure. Nevertheless, in the process of passing the IUD through the vagina and cervix, some microorganisms are likely to be introduced into the uterus (581). Thus, sterilization of IUDs reduces the risk of contamination but cannot eliminate it.

Is factory-sterilization preferable to chemical sterilization in the field? Limited data suggest that the choice makes no difference in rates of pelvic infection (365, 437). Factory-sterilization, however, can help to assure that all IUDs used are sterilized properly and can eliminate variation in sterilization technique that would occur if the devices were sterilized in the field instead (317). Bulk-packed, sterile IUDs would present new problems, however. Unless all the IUDs were inserted shortly after the bulk package was opened, the remaining devices could become contaminated (264, 317, 437). Moreover, health personnel could be misled by a package that is labeled sterile even though it has been opened and may be contaminated. As a result, they might fail to sterilize the IUDs chemically before insertion (264, 317). In addition, bulk-packed Lippes Loops are provided with reusable inserters, but these inserters should be sterilized before each re-use. Considering these problems, organizations that want presterilized IUDs would probably be wisest to use individually packaged sterile IUDs.

How much does sterile packaging add to the cost of an IUD? The added cost of individual sterile packages is almost a negligible part of the total cost for copper Ts because the extensive individual handling required in manufacturing and assembling these devices accounts for so much of the cost (264). For Lippes Loops, however, which require far less handling and are usually bulk-packed, the addition of individual sterile packaging would probably increase the cost by 250 to 300 percent (264).

In some settings, individually sterilized IUDs are clearly more convenient and easier to use than bulk-packed IUDs. Traveling health personnel, for example, can use sterile-packed IUDs more easily than bulk-packed IUDs, which require chemical sterilization. On the other hand, in clinics that perform a large number of IUD insertions, bulk-packed IUDs might be used as easily as individually sterile-packed IUDs.

Currently, for copper devices, sterile, individual packaging has proved practical. Research on methods of chemically sterilizing copper IUDs is still in the preliminary stages. Furthermore, in the field, bulk-packed copper Ts could be difficult to load in the inserters. Shipment of assembled but nonsterile copper Ts and inserters could result in confusion over whether they were sterile (264).

IPPF supplies both individually packed, sterile TCu-200s and bulk-packed Lippes Loops to its affiliates around the world. IPPF has suggested that field sterilization of bulk-packed IUDs has an advantage. It might offer an opportunity to draw attention to the importance of sterile technique and help in training personnel not to handle sterilized IUDs (423).

### Methods of Sterilizing IUDs

For bulk-packed unmedicated IUDs, cold sterilization in antimicrobial chemicals is the usual method of sterilization. Several different methods have been used, and no single antimicrobial agent is clearly established as the best. IPPF recommends immersion for 20 minutes in an aqueous iodine 1:2,500 solution or in isopropyl alcohol 75 percent (233). WHO suggests immersion for 24 hours in benzalkonium chloride 1:750 or for 10 minutes in aqueous iodine 1:2,500 (154). Robert Snowden and colleagues recommend three methods: washing in 0.1 percent benzalkonium chloride and soaking in the same solution for 24 hours; soaking in 0.1 percent benzalkonium chloride for six hours and then rinsing in the same solution; or soaking for five minutes in diluted iodine or in an iodine-iodide mixture with 0.04 percent elemental iodine, and then rinsing in sterile water (450). Inserters should be sterilized in the same way as IUDs.

Recent research by IFRP suggests that formaldehydes and chlorine-liberating compounds may be more effective methods of cold-sterilizing unmedicated IUDs. These compounds eliminated bacterial spores as well as the two bacteria tested, *Escherichia coli* and *Staphylococcus aureus*. By contrast, benzalkonium chloride did not eliminate bacterial spores and some vegetative bacteria (3).

For copper IUDs, factory sterilization is preferred (350). Research is underway to find methods of cold sterilization for use when the sterile packaging has been contaminated or if copper

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IUDs were provided in bulk, nonsterile packages. Iodine solutions are not the first choice because they can corrode copper (4). IFRP tests identified three compounds as meriting further study—one compound liberating formaldehyde and two liberating alkaline glutaraldehydes (501, 502). In the next phase of the study, these three sterilizing agents will be tested under the working conditions prevailing in family planning clinics in developing countries (4). USAID has offered to make available Sporicidin, one of the alkaline glutaraldehyde solutions (545).

Cold sterilization has several disadvantages. Many compounds are effective only against some forms of bacteria. As noted, benzalkonium chloride (marketed in the US as Zephiran Chloride Aqueous Solution) is ineffective against bacterial spores and some vegetative bacteria (3). A widely used alkaline glutaraldehyde compound (marketed in the US as Cidex Formula 7) is effective against *Escherichia coli* on copper IUDs but not on polyethylene IUDs (3). Also, IUDs must be soaked for as long as 24 hours prior to insertion. Another major problem is the need for sterile water, either to flush the chemical residue from the IUD, to dilute the antimicrobial compound before use, or both. Flushing is important because most antimicrobial compounds are skin irritants, and formaldehyde is also an eye and respiratory tract irritant (3) and is carcinogenic in rodents (43, 323, 471). Some compounds are unstable and can be used for only a few weeks after being opened (3).

### Storage

How long can IUDs be stored before insertion? No one knows, but normally both the polyethylene and copper used for most devices are inert and durable. If protected from ultraviolet light and extremes of heat and cold—especially repeated cycles of heat and cold—IUDs do not appear to change significantly for years.

Tests on sterile-packed TCu-200 IUDs conducted by the Population Council in cooperation with the Ortho Pharmaceutical Corporation found no significant changes in devices stored for 18 months at 5°C, 24°C (room temperature), 37°C, or 50°C (317). No tests have been reported on IUDs stored for longer periods or in fluctuating climates.

Repeated extremes of heat and cold—such as might occur in railroad cars, ships, or warehouses in hot climates—might change the shape or reduce the memory of the polyethylene in IUDs (298). Exposure to ultraviolet radiation—from the sun or fluorescent lights—can similarly affect polyethylene (265, 298). The packaging might also be affected. After a long period of storage, individually packed IUDs might no longer be sterile.

Currently one distributor of Lippes Loops, Ortho Pharmaceutical, lists expiration dates of three years from the time of manufacture on its products. Part of a corporate policy of date-stamping all products, the dating is intended to indicate the difficulty of guaranteeing that the device will remain stable over prolonged periods under varied storage conditions (340). Few cases have been reported of damage to IUDs from prolonged storage, however, and none have involved the Lippes Loop (545).

In conclusion, the contraceptive benefits and many medical issues associated with IUDs have been well-researched over the last two decades. In addition to the Lippes Loop, several copper-releasing and other devices have been proven safe, effective, and suitable for national family planning programs. The major problems in expanding use of IUDs in developing countries tend to be programmatic rather than scientific: identifying women at high risk of pregnancy and low risk of PID or other complications, who are the best candidates for IUD use; assuring the attention of well-trained and sympathetic health personnel both for insertion and for follow-up; and providing a regular supply of high-quality devices at affordable prices. Solving problems of supply and distribution will probably require much cooperation between donor organizations commercial manufacturers, and government regulatory and service agencies.

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CONDOM•DIAPHRAGM•FOAM•SPERMICIDE

# Population Reports

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Number 6
September-October 1982

## BARRIER METHODS

Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

# Update on Condoms—Products, Protection, Promotion

**Editors' Summary.** Condoms are a safe, effective, reversible method of birth control. In addition to preventing pregnancy, condoms protect both men and women from sexually transmitted diseases. They have no after-effects and can be used correctly without medical supervision. Yet condoms are underutilized, both in developing countries where fertility is high and in developed countries, especially among younger couples at greatest risk of sexually transmitted disease.

An estimated 40 million couples throughout the world rely on condoms. Use is heavily concentrated in a few areas, however. Two-thirds of condom users are in developed countries. Japan alone accounts for about 25 percent of the condom users in the world. China accounts for another 20 percent. This contrasts with other contraceptive methods such as oral contraceptives, which are used about equally by women in developed and developing countries, and voluntary sterilization, which is widely used in all areas except Africa. Compared with use of other methods, condom use is low in Latin America, the Caribbean, Africa, the Middle East, and most of Asia.

In the past, condoms were often ignored by the medical community and frowned on by society because they were linked in people's minds with prostitution and venereal disease. Today condoms are receiving new attention from health personnel and national family planning programs. There are several reasons for this revived interest:

- recognition that even family planning programs oriented toward maternal and child health need to offer a simple, effective, and reversible method of male contraception,
- concern over the possibility of side-effects from other family planning methods,
- high rates of sexually transmitted disease and out-of-wedlock pregnancy, especially in some parts of Latin America, the Caribbean, and Africa, and in many developed countries,
- successful commercial marketing of a wide range of high-quality condoms in many countries, particularly Japan and Sweden,
- innovative social marketing projects (selling condoms at subsidized prices through various retail outlets) that have increased both awareness of condoms and use in a number of developing countries.

### Effective When Used Regularly

Condoms can be a highly effective method of contraception if they are used correctly at every coitus. Experienced and strongly motivated older couples have had pregnancy rates as low as one or two per 100 couple-years of condom use. More commonly, couples using condoms experience a pregnancy rate of about 10 to 20 percent in the first 12 months of use. Many couples do not use condoms for long, but start with condoms because they are easy to obtain and then often shift to other methods for long-term use.

When properly used, condoms also provide protection against a broad range of sexually transmitted diseases. These include not only traditional venereal diseases, such as gonorrhea and syphilis, but also other infections such as herpes and Chlamydia. These sexually transmitted conditions are becoming increasingly common in some developed countries. Condoms also appear to prevent precancerous changes in the cervix.

The main limitation of condoms is that many men do not use them regularly or carefully, even when the risk of unwanted pregnancy or sexually transmitted disease is high. Many men consider condoms a nuisance or contend that they reduce sensation. Some married men associate condoms with extramarital sexual activity and are reluctant to use them at home. Some male adolescents think condoms might offend their partners,

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Phyllis T. Piotrow, Ph.D., Director; Walter Stender, Associate Director; Ward Rinehart, Editor.

and they have doubts about the effectiveness of condoms. Some men fail to put on condoms because they have been drinking.

### Distribution Channels Stressed

More information, better availability, and better promotion of condoms can increase condom use. Thus attention has turned to various ways of distributing condoms, including:

- commercial sales,
- family planning clinic distribution,
- community-based distribution by villagers,
- social marketing.

Commercial sales are the main source of supply in developed countries and in some developing countries as well, particularly in Latin America. Manufacturers use a variety of advertising approaches, sales outlets, and product variations to reach different types of users. In a few countries, such as Singapore and Hong Kong, family planning clinics also have distributed condoms effectively to both men and women, stressing male responsibility and the absence of side-effects. Community-based distribution programs have established volunteer or paid suppliers in villages, usually for oral contraceptives as well as condoms.

Social marketing programs use existing retail stores to sell, at a price most people can afford, condoms that have been provided by donor agencies or governments. Taking advantage of an array of promotional techniques, social marketing programs try to change the image of condoms, making them both attractive to young male users and acceptable to married couples. Names are chosen to enhance the appeal of the product—*Panther* in Jamaica, *Condor* in El Salvador, *Preethi* (joy and happiness) in Sri Lanka, and *Raja* (king) in Bangladesh, for example. The advertising and promotion carried out by social marketing programs almost always increase condom sales, although they may also generate controversy.

Social marketing programs now exist in over a dozen countries, including India, Sri Lanka, Bangladesh, Nepal, Egypt, Colombia, Jamaica, El Salvador, and Mexico. Condoms sold by three of these programs—in Jamaica, Sri Lanka, and Bangladesh—are estimated to protect from pregnancy 3 percent or more of all married women of reproductive age. Costs vary according to the size and age of the program, among other factors. For example, during the first year of operation, the Jamaican program cost about $24 (US) per couple-year of protection (CYP), while after a decade the large-scale Indian program cost $1.67 per CYP in 1978-79. Social marketing has generally been more cost-effective than clinic or community-based contraceptive distribution. In both Colombia and Thailand, in fact, subsidized condom sales through pharmacies and supermarkets in urban areas help to support other family planning activities.

### Production and Standards

An important concern for family planning and social marketing programs is maintenance of a regular supply of high-quality condoms. In the last two decades condom production and marketing have expanded. Factories in over 20 countries now have a total production capacity of about 34 million gross, or 5,000 million pieces annually. This is sufficient to meet and somewhat expand current levels of use. Condom manufacture is a capital-intensive industry that requires careful quality control. Most of current condom production capacity—about 29 million gross—is located in six countries—Japan, the United States, China, the United Kingdom, India, and South Korea.

To date, more than a dozen nations have established national condom standards to assure adequate strength, an absence of holes, secure packaging, and other qualities such as appropriate dimensions and colorfastness. Since 1974, the International Organization for Standardization (ISO) Technical Committee on Mechanical Contraceptives has sought agreement on an international condom standard. The most controversial question is how to test condom strength. Manufacturing countries generally prefer a tensile test, in which small sections of condoms are stretched until they break. By contrast, some importing countries prefer an air burst test, in which condoms are inflated like balloons until they burst. Both tests are approved by the ISO committee. Another possibility that might be suitable for testing condoms, especially in the field, is a water volume test to determine whether a condom can hold a given volume of water.

The basic issue is not how to produce or test condoms, however, since condoms made today by the major manufacturers are fully reliable if used properly. The problem for family planning programs is how to encourage those who are at high risk of unwanted pregnancy and/or sexually transmitted disease to use condoms regularly and effectively. During the 1980s many new approaches will probably be tried to encourage wider use of this simple and reliable method. **End of Editors' Summary.**

## BACKGROUND

For centuries condoms have been used to prevent pregnancy and avoid sexually transmitted diseases. Only about 50 years ago, however, did it become possible to produce condoms in large quantities, thanks to the latex rubber manufacturing process. The last three decades especially have seen mass-manufacture of high-quality condoms to serve a worldwide market. Thus the extremely reliable and widely available condom is a relatively recent achievement.

Condoms have certainly been used as prophylactics—to prevent sexually transmitted disease—for at least 400 years and as contraceptives for at least 250 years. The origin of condoms is unknown, however. Early Egyptian art showing men wearing sheaths may depict the use of condoms. The first written description of a condom, however, appeared in 1564, when the Italian anatomist Fallopio claimed that a linen sheath worn over the penis during intercourse would prevent the spread of disease (373). The first references to the contraceptive use of condoms appeared in bawdy verses published in England in the first quarter of the 18th century (206, 320, 357).

The origin of the word "condom" also is unknown. One possibility is that the term originated from the Latin word "condus," which means receptacle, in turn derived from the Persian word "kendu," or "kondu," meaning a long storage vessel made from animal intestine (137, 206). The well-known story of Dr. Condom, a 17th-century physician who provided King Charles II of England with a means to avoid illegitimate offspring, is probably fictitious (63, 137, 206).

The earliest commercially available condoms were made from animal intestinal membrane and were relatively expensive. They were familiar in European houses of prostitution as early as the 18th century and were mainly used as prophylactics against venereal disease. Condoms sold briskly in Europe throughout the 1700s. A British woman, Mrs. Philips, regularly advertised her wares in the late 1700s. In one handbill she boasted of 35 years of experience "in the business of making and selling machines (condoms), commonly called implements of safety which serve the health of her customers" (320). In his memoirs Casanova (1725–1798) mentioned using condoms as both prophylactics and contraceptives. He was not enthusiastic about them, however (82). The quality of these early animal-membrane condoms was uncertain at best. Casanova reportedly tested them first for holes by inflating them (206).

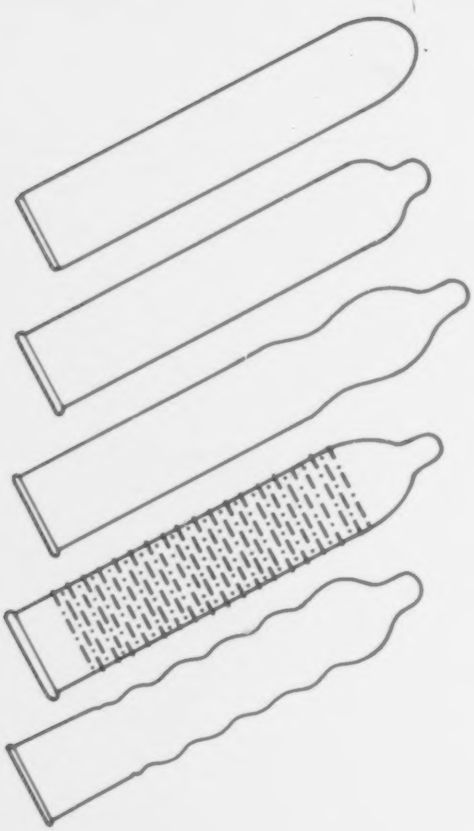
Today a few condoms are still made from animal membranes. These condoms—often called "skins"—are produced from an intestinal membrane of sheep, the caecum, which has an average thickness of about .06 mm (156). They do not shrink or stretch and are heavily lubricated to permit a close, clinging fit. While many users prefer rubber condoms, some users think that "skin" condoms transmit sensation better than rubber condoms—perhaps because they transmit body heat much as human skin does (2). These modern "skin" condoms seem to be of good quality but are difficult to test. Only limited numbers of animal-membrane condoms can be produced, and they are expensive.

### Condom Quality Improved

The development of the vulcanization process in the mid-19th century made it possible to produce rubber condoms. The flexibility and impermeability of rubber had been known for many

ढाल
preethi
PROFAM
PRESERVATIVOS LUBRICADOS
AUXILIAR EN LA PLANIFICACION FAMILIAR
PROFAM
PAGODA
SUPER
MACHO
CONDOR
Fiesta
Tops
Forget me not
CONTURE

**A great variety of condom brands are distributed around the world, supplying an estimated 40 million users. In many areas condom use is still slight, however. Extensive promotion and advertising and wider distribution through a variety of channels can encourage more use.**



**By offering a variety of shapes and textures, condom manufacturers appeal to as many potential users as possible. Some couples prefer straight-sided plain or receptacle-ended condoms. Others like contoured, textured, or rippled condoms. All come in various colors.**

years, but there had been no way to stabilize dissolved rubber particles to produce flexible sheets. During vulcanization, dissolved rubber is exposed to heat and sulfur, and the mixture stabilizes through the formation of sulfur cross-links between rubber particles. The first rubber condoms appeared on the market about 100 years ago. Since they were less expensive than condoms made from animal membranes, more men could afford them, and their use spread.

As condoms became common, they were condemned, not only as immoral, but also as dangerous. Some doctors held that all contraception (which at that time meant barrier methods) was harmful. One doctor contended that contraception caused sterility and nymphomania in women, mental decay, amnesia, and heart palpitations in men, and cancer and suicide in both sexes (354). Others singled out condoms. For example, an American physician wrote in 1870 that condoms produce "certain physical lesions from their irritating presence as foreign bodies, and also from the chemicals employed in their fabrication and other effects inseparable from their employment, oft times of a really serious nature" (163). Another American physician, in an 1885 speech on contraception, would not discuss condoms because "means which prevent the male product from entering the vagina are considered injurious ..." (90). Ironically, today the lack of side-effects is often cited as a major advantage of condoms (100, 290, 312, 444).

Although rubber condoms were widely available by the early 1900s, it is estimated that three-quarters of them were defective. Also, many deteriorated in about three months (420). In the 1930s, however, the latex process was developed. Latex is rubber tree sap that has been concentrated and stabilized. It is much easier to work with than dissolved rubber and produces thinner, longer-lasting membranes. Since the advent of latex rubber, the quality of condoms has steadily improved.

At about the same time that the quality of condoms was improving, their image was improving, too. In the US during the first quarter of the century, condoms were sold in pool halls, gasoline stations, barber shops, and similar outlets, but not in drug stores. In many states, laws made condom sales illegal. In the mid-1920s Merle Youngs, a drug store products salesman, started a US condom manufacturing company and emphasized strict quality standards. Youngs convinced druggists to sell his condoms by promising them a high-quality product (with a substantial profit margin for the druggist) that would not be sold in other outlets. Youngs' company also began court suits that voided many of the US laws against condom sales (33).

### Latex Condoms

Latex rubber condoms can be inexpensively produced in large quantities (see pp. H-144–145), making possible the mass-marketing of condoms. The thermal conductivity of rubber is less than that of animal membranes, but rubber membranes can now be produced as thin as .03 mm, although most range from .04 to .07 mm (379). Rubber condoms can be produced in various styles, such as:

- dry or lubricated,
- plain or reservoir-ended,
- straight or shaped,
- smooth or textured,
- colored or natural.

Rubber condoms can be produced in various sizes—an important advantage over animal-membrane condoms. The limited data available show differences in average penis size between regions as well as a wide range among men from the same region. In separate studies, the median erect penis length of Thai men was between 126 and 150 mm; of US men, between 151 and 175 mm. The median erect penis circumference of Thai men was between 101 and 112 mm; of US men, between 113 and 137 mm (165, 331).

Supplying condoms of the correct size is important to winning their acceptance. When the United States first began sending condoms to Asian countries, they were the same size as those sold in the US. It soon became apparent that they were too large for many Asian men. In Thailand the oversized condoms became a much publicized joke, with reports of men having to use "string to tie (the condoms) to their waist for the sake of safety" (3). Now the US Agency for International Development (USAID) supplies appropriately sized condoms to Asian countries.

Most large, international manufacturers now produce at least two basic sizes of condoms—one about 160 mm in length and 49 mm in flat width (½ circumference), officially called class II, and the other about 180 mm in length and 52 mm in flat width, officially called class I (382). With these sizes, condoms are slightly longer but somewhat smaller in unstretched circumference than median erect penis size for both Asian and Western men. In the US, manufacturers are beginning to offer the smaller sized condoms—promoting them as fitting "snugger for extra sensitivity"—and there appears to be a substantial market for them (194). In the People's Republic of China three sizes are produced. The medium size (approximately 49 mm flat width) is reportedly most popular (360).

## EFFECTIVENESS AND ACCEPTABILITY

Condoms can be a highly effective method of contraception if used regularly. They do not require medical supervision and are readily available in most towns and cities. Accidental pregnancy rates for older, consistent condom users are low. Both pregnancy and discontinuation rates are higher for younger users—mainly because young couples are more fecund, have intercourse more often, use condoms less consistently, and often switch to other methods.

Theoretical effectiveness is a measure of the likelihood that a condom may break or leak and pregnancy result. Combined results of two British studies show a rate of pregnancy resulting from broken condoms of 1.4 per 100 couple-years of use (355, 356). In other, select populations in Britain, rates of 0.4 and 0.83 pregnancies per 100 couple-years have been reported by couples who use condoms consistently (307). Estimated theoretical effectiveness rates range from 0.5 to 2 per 100 couple-years of use (197, 321, 444).

Nevertheless, there are no data indicating how often condoms actually break during use. London Rubber Corporation reportedly receives only one complaint for every million condoms sold in the UK (266). Philip Kestelman of IPPF suggests that about one in every 1,000 good-quality condoms and one in every 100 poor-quality condoms may burst during use (266).

### Use-Effectiveness

Because of inconsistent use, pregnancy rates for most condom users are higher than the low rates achieved by consistent users. In the British studies mentioned above, couples who used condoms inconsistently reported pregnancy rates of 0.8 to 6.8 per 100 couple-years (307). In the US, interviews of 18,000 women in 1973 and 1976 in the National Survey of Family Growth (NSFG) found that 9.6 percent of condom users experienced an accidental pregnancy in the first year of use (173). Rates as high as 22 per 100 couple-years of use have been reported in the Philippines and Indonesia (284, 446).

Use-effectiveness is related to a number of personal characteristics, presumably because these characteristics influence how consistently a couple uses condoms. They include age, motivation either to space or to prevent births, family income, husband's and wife's levels of education, length of marriage, and experience with the method (287, 403).

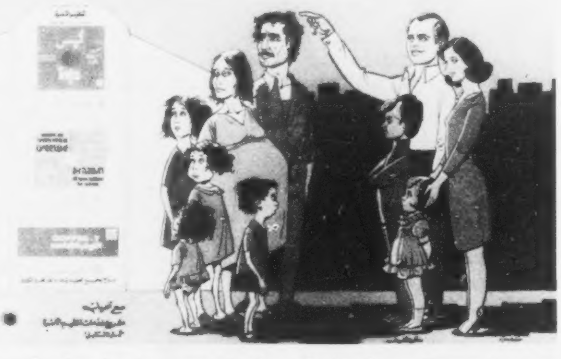
Older couples use condoms most consistently and are least fecund. Thus their accidental pregnancy rates are low. For instance, the Oxford University/Family Planning Association study in Britain found that women age 35 and older whose husbands had used condoms for more than four years had a pregnancy rate of just 0.7 per 100 couple-years of use. By comparison, the pregnancy rate for women age 25–34 whose husbands had used condoms for more than four years was 3.6 per 100 couple-years (467).

Use-effectiveness appears to be strongly related to the intention to have or not to have more children. According to the US 1970–71 National Fertility Survey, the pregnancy rate in the first 12 months of use was 10 percent for couples who were relying on condoms to prevent pregnancy compared with 21 percent for those relying on condoms to delay pregnancy (394). Among US condom users interviewed in the 1973 and 1976 surveys, first-year pregnancy rates were 7.1 per 100 couples trying to prevent pregnancy and 12.3 per 100 couples trying to delay pregnancy (173). When motivation to prevent more births is combined with older age and relatively high income, condom use is extremely effective. For US women age 30 or older who were relying on condoms to prevent any more births and had a family income greater than $15,000 (US), the first-year pregnancy rate was 0.9 per 100 women—second only to the rate of 0.8 for oral contraceptive (OC) users of the same status. For all women relying on condoms the pregnancy rate was 9.6, or 10 times higher (403).

The strength of motivation to avoid pregnancy also may be reflected in the results of a 1975 survey of almost 5,000 British women. Those who had had one or two pregnancies and who relied on condoms experienced unintended pregnancies at the rate of five per 100 women in one year—close to the rate of four per 100 for all users of oral contraceptives. By contrast, women relying on condoms who had not been previously pregnant experienced unintended pregnancies at the rate of 14 per 100 women (71).

Similar patterns have been found in developing countries. Older couples (who presumably are strongly motivated to prevent births) are the most successful condom users. For instance, in a recent analysis that combined World Fertility Survey data for five Latin American countries—Colombia, Costa Rica, the Dominican Republic, Panama, and Peru—the pregnancy rate among condom users for the 12 months after marriage or a birth was 17 per 100 women under age 30 compared with 7 per 100 women age 30 or above (171). An Indonesian survey found that, where the wife was age 15–24, 38 percent of couples using condoms experienced a pregnancy in one year, compared with 13 percent of couples where the wife was age 25–35 (446).

The effectiveness of condoms may be increased by using a spermicide along with the condom. If spermicides have a theoretical pregnancy rate of 5 per 100 couple-years of use and if both condoms and spermicides are used regularly, then combined use should be 20 times more effective than using condoms alone. Since pregnancy rates of consistent condom users are already low, it would be difficult actually to measure the added effectiveness of combining spermicide with condom use, however (376). The tradeoff in convenience and cost may not be worth the slight improvement in effectiveness (84 156, 290). While some couples may want to combine the two methods for extra protection, in other cases to *insist* that spermicides be used with condoms might actually inhibit consistent use and therefore lead to higher pregnancy rates (151, 260). Condoms lubricated with spermicide have been available in Britain since the late 1970s and will soon be available in the US. Presumably



**"Family planning is a necessity for a better future," says a poster created by a commercial advertising firm for the Egyptian Family of the Future Program. This social marketing program sells *Amaan* spermicidal tablets and copper-T IUDs as well as *Tops* condoms.** (Family of the Future/Porter, Novelli & Associates) the spermicide helps prevent pregnancy if the condom breaks or is improperly used (494).

### Continuation

Continuation rates for condoms are often lower than continuation rates for IUDs or oral contraceptives. Some couples discontinue use because of dissatisfaction with the method. Others deliberately use condoms for only a short time—between marriage and a planned pregnancy, between pregnancies, or before switching to a more permanent method. Some couples alternate condoms with the rhythm method or with other barrier methods of contraception, which makes continuation rates difficult to measure.

Continuation rates are related to many of the same factors, such as motivation and age, that influence use-effectiveness (446). For instance, of 397 highly motivated older British couples who were recruited to use spermicidally lubricated condoms, only

## INSTRUCTIONS FOR CONDOM USE

All reversible contraceptive methods require some instructions for use, ranging from the simple, as for injectables, to the relatively complex, as for modern periodic abstinence methods (302). Instructions for condom use are fairly simple, but they are important. Therefore easy-to-follow directions should be provided with all condoms. Some major manufacturers include instructions with the condoms that they distribute. Only two national standards—in Australia and Great Britain—currently require instructions in condom packages (72, 433) (see Table 6, pp. H-146-147). The international standard for packaging and labeling, developed by the International Organization for Standardization (ISO), does require them, however (233) (see p. H-148). In countries such as Nepal and Bangladesh, where many people cannot read, social marketing programs have distributed pictorial as well as written instructions (383, 476).

Some questions about proper condom use are not easily resolved and deserve special attention when preparing condom instructions: When should a condom be put on? Should a space be left at the tip of a condom when it is put on? Should a condom user withdraw immediately after ejaculation? Can condoms be reused?

When should the condom be put on? For contraceptive purposes, the condom theoretically needs to be put on only before ejaculation, but the traditional advice—put the condom on before any genital contact—may still be the best. There has been no confirmation of the common belief that viable sperm are present in the pre-ejaculatory fluid—the clear, mucoid fluid that oozes from a man's urethra during sexual arousal. Recent studies have found no motile sperm in pre-ejaculatory fluid provided the man has urinated since his last ejaculation (92, 156). Still, advising all men that they need to put on a condom only before ejaculation is not practical, since men differ in their ability to anticipate and control ejaculation (213).

For prophylactic purposes, the condom *must* be worn during all genital contact. This is because sexually transmitted diseases may be communicated by contact with genital lesions, as in the case of syphilis and herpes, or by contact with vaginal or urethral discharge, as in the case of gonorrhea.

Should a space be left at the tip of a condom when it is put on? Instructions routinely advise that, if receptacle-ended condoms are not used, space should be left at the tip. Also, it is usually recommended that air be expelled from the space or from the nipple of a receptacle-ended condom. Supposedly, if this is not done, the ejaculate may cause excess stress on the tip of a condom or semen may be forced down the side of a condom. There is no evidence concerning whether this happens, however. Any space left at the tip of a condom is probably flattened against the vaginal wall during intercourse. Also, since condoms generally are very strong and elastic, it is unlikely that one would break due to the force of ejaculation or that semen could spread to the base of a condom while a man's penis is erect (261, 263). Therefore it seems likely that having an airless space at the tip of a condom makes little difference to effectiveness.

Should a condom user withdraw immediately after ejaculation? Instructions often advise this on the grounds that prompt withdrawal avoids seepage of semen from the open end of a condom after the penis becomes flaccid. Philip Kestelman of the International Planned Parenthood Federation calls this recommendation "quite unnecessary and cruel." He argues that, as long as the condom is firmly held against the base of the penis during withdrawal, seepage is unlikely (261, 263). Of course, care must be taken that the condom does not dislodge from the penis before withdrawal.

Should condoms be reused? Reuse of disposable condoms is not recommended (84) and may be particularly unwise when condoms are being used for protection against disease (199). If, because of short supply or financial necessity, condoms must be reused, they should be carefully washed, rinsed, blotted dry, powdered (if possible), and rerolled (213). A package insert from the People's Republic of China describes how they should be handled:

> Wash thoroughly and dust with bathing powder . . . Store in a shaded, cool, dry place, preferably in an airtight container to avoid insects and deterioration. Do not use if found stuck together or yellowed. (360)

### How to Use Condoms

- Keep a supply of condoms at hand, ideally in a cool, dry place, so that a condom is easily available for use at every intercourse.
- Do not test a condom by inflating or stretching it. Handle it gently and keep it away from sharp fingernails.
- For maximum effectiveness, put the condom on before genital contact. Either the man or the woman may put the condom in place.
- Unroll the condom on the erect penis. The condom must be placed with the rolled portion out so that it will unroll properly.
- If desired, lubricate the outside of the condom using contraceptive jelly or another water-soluble lubricant.
- After ejaculation, be sure that the condom does not become dislodged from the penis. Hold the rim of the condom firmly against the base of the penis during withdrawal.
- Check the condom for tears before throwing it away. If it has torn, insert a contraceptive suppository, jelly, or foam into the vagina immediately.

three discontinued in two years (376). By contrast, among 2,057 women age 25–35 who were recruited to switch to condoms from other contraceptives, after one year only 37 percent were still relying on condoms. Almost 40 percent shifted to "a more effective" method (169).

In developing countries, continuation rates generally are lower than in developed countries, but, as in the developed countries, many couples who discontinue switch to other methods. In the Philippines, for instance, condom continuation rates at one year were 29 percent in 1974 (287) and 23 percent in 1976 (344). The majority of couples discontinued because they did not like using condoms. Of the 77 percent who discontinued in 1976, however, 36 percent switched to other methods. In fact, in some developing countries the all-method continuation rates (continuation of any contraceptive method) are only slightly lower for those who start with condoms than for those who start with oral contraceptives. According to 1976 surveys, in the Philippines the 12-month all-method continuation rate was 51 percent for those who started with condoms and 61 percent for those who started with oral contraceptives (344); the corresponding figures in Indonesia were 63 and 66 percent (446).

In some developing countries continuation rates might be higher if a regular supply of condoms was assured in both rural and urban areas (188, 344). For instance, in Ghana the Danfa project provided contraceptive services to rural villages through health centers, health posts, and mobile teams. A continuation rate of 69 percent after one year was reported for condom users. Of the men who discontinued condom use, 24 percent said that they did so because they could not obtain regular supplies (289).

### Acceptability

The main reason condoms are not more effective is inconsistent use. Both inconsistent use and unwillingness to use condoms at all are evidence that the method may not be as acceptable as other methods of family planning. Among the reasons that people cite for not using condoms are:

- decreased male—and female—sensitivity during coitus,
- inconvenience of the method—the need to use a condom at every coitus, to put it on during lovemaking, and to store and dispose of it,
- the poor image of condoms due to their traditional association with venereal disease and prostitution,
- misconceptions about condom effectiveness and side-effects.

**Decreased sensitivity** is a common complaint of both condom users and nonusers (96, 156, 270, 390). For instance, a US survey of 1,874 men and women found that 63 percent of men and 33 percent of women felt that condoms reduce sensation. In the same survey, however, 38 percent of men and 14 percent of women saw reduced sensation as an advantage since it prolongs intercourse (2). The advantage of prolonging intercourse was also noted by some Egyptian condom users interviewed for the social marketing program (372). Long-term users appear to be less bothered by decreased sensation. As a Philippine man put it, "After some time, using the condom becomes natural. I myself have gotten accustomed to it" (390).

Whether condoms really do reduce sensation and, if so, how much, has never been precisely measured. Presumably, the thinner the condom, the less reduction in sensation. Certainly that is what many men think. A common complaint heard by family planning programs is that the condoms they provide are too thick. For example, in South Korea, half of over 1,000 men interviewed about condom use complained that government condoms were too thick (270). In Japan, the effect of thin condoms on acceptability was dramatically illustrated. Sales jumped 43 percent in one year after condoms advertised as having a thickness of .03 mm were introduced (277). These condoms are about .02–.03 mm thinner than standard condoms (379).

**More and more, women are providing condoms to other women. In Japan, for example, saleswomen sell condoms to housewives at home. Here, a worker for the Centro de Pesquisas de Assistência Integrada para à Mulher e à Criança in Rio de Janeiro, Brazil, offers a woman a month's free supply of condoms.** (Courtesy of Maria Wawer)

Lubricated condoms have proved more popular than unlubricated ones, perhaps because the lubrication substitutes for sensitivity. For example, at a US sexually transmitted disease clinic, patients preferred lubricated condoms because those condoms felt more comfortable and allowed better sensation during intercourse (110).

Another objection to condoms is the **inconvenience or troublesomeness of the method** (156, 270). Fifty percent of nonusers responding to a questionnaire in a popular US magazine felt that a major disadvantage of condoms was the interruption in lovemaking required to put them on. Others complained that condoms are messy (110). In communities where there is little privacy in housing and no waste disposal services, the need to store and dispose of condoms also makes them awkward to use (479).

Although the inconvenience associated with condom use cannot be completely eliminated, it can be reduced. Manufacturers now produce condoms with "dry," silicone-based lubrication that is less messy than wet lubrication. Packaging improvements can make condoms easier to unwrap and put on quickly—adequate serration between inner packets and indications of which side of a rolled condom is "up," so that it can be unrolled on the penis correctly (28). Attractive, discreet packaging, perhaps with enclosed disposal bags, as many Japanese brands offer, also can make using condoms less troublesome.

The **poor image** of condoms may also be a problem. It has been reinforced for centuries by physicians and others who proclaimed condoms immoral (163, 206, 320) and by laws banning their sale or mandating that they be "sold only for the prevention of disease" (33, 206). Many men take the attitude that condoms should be used only outside of marriage. As a Philippine man said during a group discussion, "Condoms should be used only with prostitutes, not with your wife" (390). In the US over 40 percent of 420 male adolescents felt that using a condom showed disrespect for their partner (139). This poor image can be changed only through promotional campaigns making it clear that condoms are a respectable means of family planning. The success of such campaigns in the US and Japan is evidenced by the fact that in the US one-third of condoms are sold to women and in Japan perhaps one-fifth are sold to housewives by door-to-door saleswomen (33, 275, 373).

**Misconceptions** about the effectiveness and side-effects of condoms are widespread. In Indonesia a pilot project that distributed condoms in answer to mail orders received many questions about how often condoms leak (180). In Philippine discussion groups men commented that condoms are not strong because they are so thin. Some thought that condoms should be inflated with air to test them before use (390). In the US as well, many young men think that condoms break easily and that each one should be tested before use (138, 327). Not only is this not necessary, but also it may damage the condom and cause it to break during use. In Bangladesh a pilot distribution project (taking place before the social marketing program was well established) found that most couples who received free condoms did not use them. One reason was traditional beliefs—for example, that "semen is a necessary health tonic for women" and that "condom use can cause impotence" (383). Promotional activities that stress the quality and safety of condoms may help to counteract such misconceptions.

**In this Sri Lankan shop, a self-service display of *Preethi* condoms has been set up next to supplies of eggs, razor blades, and light bulbs. Such displays help customers find and buy condoms easily.** (IPPF/Mark Edwards)

The acceptability of condoms can undoubtedly be maximized by providing good-quality, conveniently packaged condoms in a variety of styles and by promoting them as safe, reliable, and easy—even fun—to use, as the major manufacturers and social marketing programs are now doing. Free samples and bold point-of-purchase displays will entice many men to try condoms. In Mexico and Colombia, where surveys at first suggested that condoms would be highly unacceptable to most potential users, such promotions have changed attitudes, as evidenced by much greater condom sales than some had thought possible (109). Offering a variety of products and advertising them to various markets also seems to be important. Japanese manufacturers have pioneered in promoting condom use as fun and pleasurable for both men and women, mainly by developing and advertising condoms of various colors, shapes, and textures. In this way, they appeal to as many potential users as possible.

## PROTECTION AGAINST DISEASE

Traditionally, the term venereal disease has been used to refer to five diseases that are transmitted primarily by genital contact—syphilis, gonorrhea, chancroid, granuloma inguinale, and lymphogranuloma venereum (LGV). Researchers and clinicians now prefer the term sexually transmitted disease (STD). The term STD is preferred mainly because it avoids some of the stigma attached to the term venereal disease (103) and because it emphasizes the wide range of conditions that can be spread by sexual contact. These include herpes, trichomoniasis, candidiasis (a fungal infection of the vagina), and nongonococcal urethritis as well as the traditional venereal diseases.

The use of condoms provides considerable protection against sexually transmitted diseases. The evidence comes from both past and recent studies. For example, in the early 1970s a French study of the sexual partners of over 700 women infected with gonorrhea or trichomoniasis revealed that less than one percent of the 302 men who claimed to have consistently used condoms contracted gonorrhea, and only 2 percent contracted trichomoniasis. Of the 480 men who did not use condoms, 97 percent contracted gonorrhea, and 33 percent, trichomoniasis (421). In a retrospective study of 246 sexually active Australian soldiers who served in Vietnam, none of the 55 who said that they always used condoms contracted an STD. Of the 191 who did not use condoms, 35 percent contracted an STD—for the most part gonorrhea or chancroid (a common STD in tropical areas). Occasional use of condoms or washing after intercourse appeared to make little difference (190). Studies of patients diagnosed at STD clinics in London and Belfast found that those who had no STD were more likely to have used condoms than those with gonorrhea or syphilis. The relative risk of having an STD was about 0.4, or less than half as great, indicating a protective effect of condom use (56, 358). In the US an investigation of 2,019 women attending a Louisiana family planning clinic showed that women who used a diaphragm or whose partners used condoms had cervical gonorrhea about one-fifth as often as pill users or IUD users (254).

Just how well condoms protect against STDs is difficult to gauge. The chief problem is that most studies involve retrospective interviews with military personnel or STD clinic patients. Since these studies rely entirely on written or verbal reports of condom use, it is impossible to be sure how regularly the participants used condoms. The importance of regular use is illustrated in the London clinic study. For men who said that they used condoms regularly and correctly, the condom had a strong protective effect against gonorrhea or syphilis—a relative risk of 0.1 compared with nonusers. For those who used condoms irregularly or incorrectly, the protective effect was far less—a relative risk of 0.8 (56). In addition, many STDs can be transmitted to or from the genitals to other parts of a sexual partner's body, especially mucous membranes such as those in the mouth or anus. In most populations, however, the great majority of transmissions involve genital-to-genital contact (216, 431). Therefore, most people would be protected against STDs by using a condom throughout coitus.

Some have argued that the protection provided by condoms is better for some STDs than for others. Specifically, it has been suggested that syphilis is more likely to be transmitted nongenitally than other STDs, and therefore condoms may provide less protection against syphilis (191, 213, 345, 420). Others have challenged this, pointing out that cases of nongenitally transmitted syphilis are rare (216, 431). In both the London and Belfast clinic studies the number of syphilis cases was small, but the protective effect against syphilis was at least as strong as the effect against gonorrhea (56, 358).

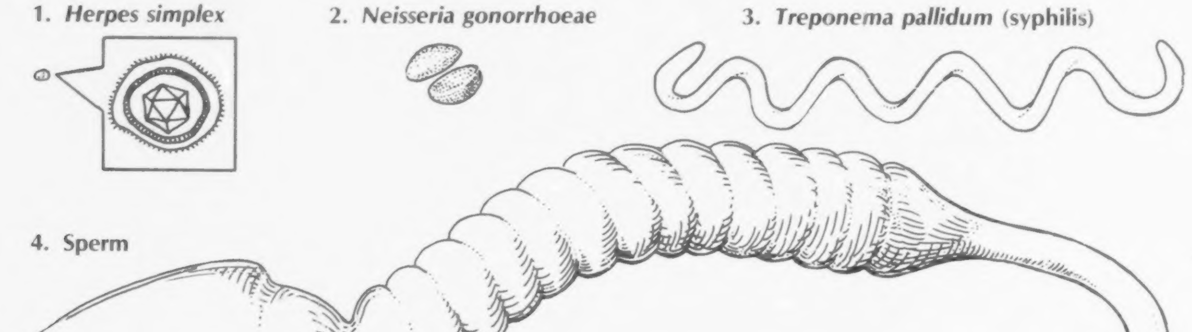
It also has been suggested that the smallest disease-causing organisms—such as *Herpes* virus—may be able to pass through pores in condom membranes (56). This is unlikely, however. A *Herpes* virus has a diameter of about 0.1 microns (or one ten-thousandth of a millimeter) and the organisms causing nongonococcal urethritis—*Chlamydia* and *Ureaplasma urealyticum*—have diameters of about 0.2 microns. By comparison, a gonococcus has a cell diameter of about 0.8 microns, and the head of a sperm has a diameter of about 3 microns (see drawings, this page). Water and air molecules, however, are about 1,000 times smaller than a *Herpes* virus. Since good-quality condoms are watertight and airtight, it is unlikely that organisms such as *Herpes* virus could pass through them (99). This is important since the incidence of herpes is increasing in developed countries and there is currently no known cure for recurrent herpes lesions.

Of the few small clinical studies addressing the effectiveness of condoms against very small microorganisms, most but not all have shown a protective effect. A study of 191 sexually active US college students found that 43 percent of men who did not use condoms were infected with *Ureaplasma urealyticum* (T-mycoplasma), an organism thought to cause nongonococcal urethritis, compared with 14 percent of those who said that they always or almost always used condoms (319). Data from the London clinic study suggested a protective effect against nonspecific urethritis only if condoms were regularly and correctly used (56). The Belfast clinic study showed no protective effect against nongonococcal urethritis (358).

Concerning herpes, in the London study men with herpes were less likely to have used condoms than men with no STD (56). Two in vitro studies also suggest that condoms can protect against genital transmission of *Herpes* virus. In one study a condom containing *Herpes* virus was suspended in a nutrient broth. Although the virus remained viable inside the condom for up to 24 hours, none could be cultured from the outside medium (424). In the other study an attempt was made to simulate the stress that coital movement places on a condom. A condom containing *Herpes* virus was placed around the plunger of a syringe, then nutrient broth was sucked in and out of the syringe 50 times. No virus was found in the broth (99, 101).

### Condoms and Limiting the Spread of STDs

Since individuals who use condoms consistently are protected against most STDs to some extent, widespread use should slow the rise in STD rates now taking place in some countries (see


**1. *Herpes simplex***

**2. *Neisseria gonorrhoeae***

**3. *Treponema pallidum* (syphilis)**

**4. Sperm**

**Used correctly at every coitus, condoms protect against sexually transmitted diseases, even though some disease-causing organisms are much smaller than sperm. A *Herpes simplex* virus is only about 0.1 micron wide (1). *Neisseria gonorrhoeae,* which causes gonorrhea, is about 0.8 micron wide (2). *Treponema pallidum,* which causes syphilis, is about 0.2 micron wide (3). By contrast, a sperm is about 3 microns wide (4).**

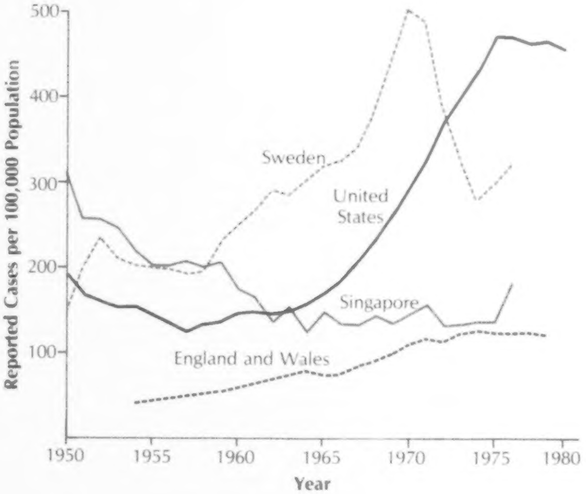
Figure 1). Although a direct correlation between increased condom use and decreased STD rates would be difficult to demonstrate, condom use may have contributed to the decrease in the gonorrhea rate in Sweden in the early 1970s. As part of an overall effort to reduce the STD rate, a campaign to encourage condom use was started in 1970. Within two years the number of condoms sold had increased by 50 percent, and the incidence of gonorrhea had dropped by 20 percent (207). Other factors that may have contributed to this drop in gonorrhea incidence include a greater willingness to seek treatment and to urge partners to seek treatment, more treatment facilities and trained personnel, and better education about STDs in Swedish schools. In 1975, however, gonorrhea rates began to rise again, for unknown reasons (472).

According to a theoretical model, if the risk per week of acquiring gonorrhea were 27 percent and 25 percent of at-risk individuals used a 50 percent effective prophylactic, the prevalence of gonorrhea would drop by about 80 percent in one year. Almost all cases would be eliminated in four years (294).

For a number of reasons this model may overestimate the impact of prophylaxis. Most important, there appears to be a core of individuals among whom gonorrhea prevalence is very high—about 20 percent (316, 490). The major obstacle to reducing gonorrhea rates through condom use is that these individuals rarely use condoms. Surveys of STD clinic patients find that many are indifferent or even averse to using condoms, even when they know that condoms protect against STDs (56, 111, 128, 136). Thus these individuals contribute disproportionately to the spread of gonorrhea and probably many other STDs.

Doubts about the effectiveness of condoms and their impact on sensation contribute to nonuse of condoms among some high-risk individuals (110, 111, 136, 207). So do the effects of alcohol and drugs. Studies of STDs in military populations show that, if men are drunk, they are unlikely to use condoms even when they have condoms with them at the time (105, 190).

**Figure 1. Gonorrhea Rates in Selected Areas, 1950–1980**



Sources: Sweden: UN (502), Wallin (472).
US: US Public Health Service (461). Civilian cases only.
Singapore: Morton (498), Rajan et al. (499), UN (502).
England and Wales: Department of Health and Social Security (497), Morton (498), Smith (501). Data for 1972–78 for England only.

**Reported gonorrhea rates in four areas show markedly different trends. Rates rose rapidly in the US and Sweden but then declined in Sweden in the early 1970s, when a campaign for more information, treatment, and condom use was conducted. In Singapore rates have slowly declined, while in England and Wales they have slowly risen. Changes in case reporting can affect these rates.**

Because of the problem of nonuse or inconsistent use, the effect of condoms on the spread of STDs is difficult to estimate. As Gavin Hart states:

> The actual reliability of use of effective prophylactics, particularly by promiscuous individuals, has restricted their influence on disease control. Since universal utilization is unlikely, their potential impact is complex and difficult to predict. (191)

### Protection Against PID and Amniotic Fluid Infections

Sexually transmitted diseases are an important cause of pelvic inflammatory disease (PID) in women. Sexually transmitted organisms also may cause amniotic fluid infection in pregnant women. Women whose partners use condoms have less risk of acquiring these infections.

PID, an infection of the uterus or fallopian tubes, may lead to infertility or ectopic pregnancy as a result of totally or partially obstructed tubes. It is often caused by sexually transmitted organisms including *Neisseria gonorrhoeae* and *Chlamydia* (129). Some or all of the organisms that cause PID may be carried through the cervix by sperm (452). Condoms protect women against PID by preventing both sperm and PID-causing organisms from reaching the cervix (293). A recent case-control study, comparing 306 women who had been treated for PID with 1,175 controls, demonstrated the protective effect. Women who used various barrier methods had a 0.6 relative risk of PID when compared with women using no contraceptive method. Those relying on condoms had a relative risk of 0.6, diaphragm users had a relative risk of 0.4, and spermicide users had a relative risk of 0.7 (255).

Condom use during pregnancy may protect against amniotic fluid infections (333). These infections are caused by a variety of bacteria. Some—such as *Chlamydia*—are sexually transmitted, and others—such as *Escherichia coli*—are normally present in the ano-genital area (334, 336). Infection is especially likely during late pregnancy, when the cervix shortens and the cervical os begins to open.

Amniotic fluid infections in late pregnancy are a greater problem in many developing countries than in developed countries (336). Undernourished women appear to be especially susceptible, in part because zinc deficiencies reduce the antibacterial properties of amniotic fluid (44, 336, 404). In some African countries the mortality of babies exposed to infection is especially high (334). For instance, bacterially caused amniotic fluid infection is the single greatest cause of perinatal deaths in Addis Ababa, Ethiopia, where one in 12 infants is stillborn or dies shortly after birth (334). In a study of the effects of condom use on the prevalence of these infections, a group of 551 Zulu women in urban South Africa were offered free condoms and advised to have their partners use them to prevent infection and harm to their babies. Of these women, 48 percent of those who had coitus three or four days before delivery without using condoms developed infections, compared with 19 percent of condom users and 18 percent of those who abstained. Other complications such as low birth weight and preterm delivery also were more common among the first group (335).

### Condoms and Cervical Cancer

Recent studies indicate that condoms have a preventive and possibly also a therapeutic effect on cervical cell abnormalities. Cervical cancer appears to be initiated or promoted by some sexually transmitted agent (61, 140, 258, 387). The agent may be *Herpes* virus, which often is present in the cervical tissue of patients with neoplasia (49, 259, 337). Clinical studies show that women who rely on barrier methods of contraception, including condoms, are less likely to develop cervical cancer or its precursors than are other women. This suggests that barrier methods limit transmission of an agent responsible for abnormal cellular development.

Women who have relied on barrier methods for at least five years appear to have a lower risk of developing cervical dysplasia (abnormal cells) or carcinoma than women who have used other contraceptives. In a British case-control study the relative risk (adjusted for age) of developing cervical abnormalities decreased with duration of condom or diaphragm use, while it increased with duration of oral contraceptive (OC) use (187).

| Years of Use | Relative Risk of Severe Cervical Dysplasia Using: | |
|---|---|---|
| | Barrier Methods | OCs |
| **None** | 1.0 | 1.0 |
| **<5** | 0.9 | 1.1 |
| **5–9** | 0.4 | 3.6 |
| **10+** | 0.2 | 4.0 |

This trend was also observed when condom and diaphragm use were considered separately as well as when data were adjusted for the number of sexual partners (187). A second case-control study, drawn from Oxford University/Family Planning Association study data, also suggested that the diaphragm—and therefore perhaps other barrier methods—protects against cervical neoplasia. Rates per 1,000 woman-years of observation for all types of cervical neoplasia were:

| | |
|---|---|
| **All women** | 0.73 |
| **OC users** | 0.95 |
| **IUD users** | 0.87 |
| **Diaphragm users** | 0.17 |

Diaphragm users were less likely to have had coitus at an early age or to have had as many sexual partners as users of other contraceptives. When the effects of these factors plus the effects of smoking were taken into account, the estimated relative risk for diaphragm users compared with users of other contraceptives was 0.23. The majority of women studied had used a diaphragm for five or more years (483).

One recent study has suggested that condom use also may help to reverse the progression of cervical cell abnormalities. Among 139 women with cervical cell abnormalities of varying severity whose partners began using condoms and who received no other treatment, 136 showed reversion, and 125 had no recurrence an average of 39 months after biopsy (387). Further study, involving a comparison group and with more detailed analyses of the various degrees of cellular abnormality, will be needed to confirm these findings.

### Infertility Therapy

Condoms might also be useful in treating women who become infertile because they produce antibodies to sperm. An estimated 10 to 30 percent of unexplained infertility may occur because antibodies that incapacitate sperm develop in the cells or blood sera of women or, less commonly, men (42, 242, 243, 299). Since antibodies appear to be produced when sperm come in contact with cervical tissue, it has been suggested that using condoms should allow sperm antibody levels (titers) to drop (149, 272, 299).

In one of the earliest investigations of the relationship between infertility and sperm antibodies, 15 of 19 women with unexplained infertility were found to have high levels of sperm antibodies. Five of these women's husbands used condoms for 60 days to six months and then timed unprotected intercourse to coincide with ovulation. All five showed a marked reduction in sperm antibody titer during condom therapy, and three became pregnant (149). Numerous investigations since have reported similar, although usually less marked, results (168, 189, 272, 407, 423). Nevertheless, a number of questions about sperm antibodies raise doubts about the effectiveness of condom therapy. For example,

- After condom therapy, antibody levels have been observed to rise immediately after unprotected coitus. Thus the likelihood of pregnancy occurring is often very slim (31, 148, 174).
- Some women with sperm antibodies have experienced a drop in antibody titer and/or a pregnancy without therapy (184, 243, 299).
- Some of the tests used to measure sperm antibodies are imprecise (184, 243).

The mechanism that results in sperm antibody-related infertility is still not well understood (42, 242, 243, 299, 423). Nevertheless, one expert estimates that a woman who has a high sperm-antibody titer probably can increase her chances of becoming pregnant from about 20 percent to about 30 percent if her partner uses condoms for at least three months or until the titer drops (146). Although the probability of a pregnancy remains small, condom therapy is inexpensive, involves no risk of adverse side-effects, and may help some infertile couples.

## USE

There are currently almost 40 million condom users throughout the world (see Table 1). This estimate is based on the most recent surveys of representative population samples.

**Table 1. Estimated Number of Condom Users Worldwide, 1981**

| Region | Estimated % of MWRA Relying on Condoms | Estimated Number Relying on Condoms (in 1,000s) |
|---|---|---|
| **AFRICA** | 0.3 | 150 |
| **ASIA** | | |
| **China** | 6 | 7,300 |
| **Indian subcontinent** | 1 | 1,700 |
| **Taiwan** | 12 | 300 |
| **Other Asia** | 5 | 3,100 |
| **Region** | 4 | 12,400 |
| **LATIN AMERICA & CARIBBEAN** | | |
| **Brazil** | 1 | 200 |
| **Other Latin America** | 3 | 700 |
| **Caribbean** | 6 | 300 |
| **Region** | 2 | 1,200 |
| **MIDDLE EAST & NORTH AFRICA** | 0.5 | 200 |
| **DEVELOPED COUNTRIES** | | |
| **Japan** | 50 | 10,400 |
| **Australia & New Zealand** | 7 | 200 |
| **Eastern Europe** | 7 | 5,000 |
| **Northern Europe** | 21 | 2,700 |
| **Western Europe** | 9 | 4,000 |
| **US & Canada** | 7 | 3,000 |
| **All developed countries** | 13 | 25,300 |
| **TOTAL** | 6 | 39,250 |

MWRA = married women of reproductive age

## Table 2. Percentage of Married Women of Reproductive Age Whose Partners Use Condoms, as Reported in Representative Sample Surveys, 1970-1981

|  |  |  | % Using |  | % of Contraceptors Using Condoms[a] |
|---|---|---|---|---|---|
| Region & Country or Area | Ref. No. | Year | Any Method | Condom |  |
| AFRICA |  |  |  |  |  |
| Kenya | 257 | 1977-78 | 7 | 0 | 2 |
| Lesotho | 301 | 1977 | 7 | 0 | 3 |
| Mauritius | 202 | 1975 | 46 | 5 | 11 |
| Senegal | 301 | 1978 | 4 | 0 | 2 |
| Sudan (North) | 301 | 1978 | 5 | 0 | 3 |
| ASIA & PACIFIC |  |  |  |  |  |
| Bangladesh | 81 | 1975-76 | 8 | 1 | 13 |
|  | 53 | 1979 | 13 | 2 | 12 |
|  | 53 | 1981 | 19 | 2 | 9 |
| Fiji | 81 | 1977 | 41 | 6 | 15 |
| Hong Kong | 209 | 1977 | 71 | 13 | 18 |
| Indonesia | 81 | 1976 | 26 | 2 | 8 |
| Korea, Rep. of | 81 | 1974 | 37 | 6 | 16 |
|  | 329 | 1979 | 54 | 5 | 10 |
| Malaysia | 81 | 1974 | 33 | 3 | 9 |
| Nepal | 81 | 1976 | 2 | 0 | 0 |
| Pakistan[b] | 81 | 1975 | 5 | 1 | 20 |
| Philippines | 81 | 1978 | 36 | 4 | 11 |
| Singapore | 87 | 1973 | 60 | 17 | 28 |
|  | 87 | 1977 | 71 | 21 | 29 |
| Sri Lanka | 81 | 1975 | 32 | 2 | 6 |
| Thailand | 81 | 1975 | 36 | 0 | 0 |
|  | 329 | 1978 | 53 | 2 | 4 |
| LATIN AMERICA & CARIBBEAN |  |  |  |  |  |
| Barbados | 127 | 1971 | 30 | 5 | 18 |
|  | 106 | 1981 | 47 | 5 | 11 |
| Brazil |  |  |  |  |  |
| Bahía | 391 | 1980 | 31 | 1 | 5 |
| Paraiba | 391 | 1980 | 43 | 0 | 0 |
| Pernambuco | 391 | 1980 | 41 | 1 | 1 |
| Píauí | 329 | 1979 | 31 | 0 | 0 |
| Rio Grande do Norte | 391 | 1980 | 47 | 1 | 1 |
| São Paulo | 329 | 1978 | 64 | 7 | 10 |
| Colombia | 81 | 1976 | 45 | 2 | 4 |
|  | 329 | 1978 | 48 | 2 | 3 |
|  | 106 | 1981 | 51 | 1 | 2 |
| Costa Rica | 81 | 1976 | 66 | 9 | 14 |
|  | 329 | 1978 | 65 | 9 | 14 |
|  | 106 | 1981 | 66 | 9 | 13 |
| Dominican Republic | 81 | 1975 | 32 | 2 | 6 |
| El Salvador | 329 | 1978 | 34 | 2 | 4 |
| Guadeloupe | 86 | 1976 | 44 | 6 | 13 |
| Guatemala | 329 | 1978 | 18 | 1 | 4 |
| Guyana | 81 | 1975 | 31 | 0 | 0 |
| Haiti | 181 | 1977 | 27 | 2 | 6 |
| Honduras | 106 | 1981 | 25 | 0 | 1 |
| Jamaica | 81 | 1975-76 | 40 | 7 | 18 |
|  | 329 | 1979 | 55 | 7 | 12 |
| LATIN AMERICA & CARIBBEAN (Continued) |  |  |  |  |  |
| Martinique | 86 | 1976 | 51 | 5 | 9 |
| Mexico | 81 | 1976-77 | 33 | 1 | 3 |
|  | 329 | 1978 | 41 | 1 | 3 |
| Panama | 81 | 1976 | 55 | 1 | 2 |
|  | 329 | 1979-80 | 61 | 2 | 3 |
| Paraguay | 329 | 1977 | 24 | 2 | 8 |
|  | 81 | 1979 | 39 | 2 | 5 |
| Peru | 81 | 1977-78 | 31 | 1 | 3 |
| Puerto Rico | 377 | 1974 | 61 | 3 | 5 |
| Trinidad & Tobago | 186 | 1970 | 40 | 9 | 23 |
|  | 454 | 1977 | 61 | 18 | 29 |
| Venezuela | 466 | 1977 | 60 | 6 | 10 |
| MIDDLE EAST & NORTH AFRICA |  |  |  |  |  |
| Egypt | 106 | 1981 | 15 | 0 | 2 |
| Jordan | 81 | 1976 | 25 | 1 | 4 |
| Syria | 395 | 1973 | 23[c] | 1 | 3 |
|  | 301 | 1978 | 23 | 1 | 3 |
| Tunisia (Jendouba) | 329 | 1979 | 32 | 0 | 1 |
| Turkey | 179 | 1978 | 50 | 4 | 8 |
| DEVELOPED COUNTRIES |  |  |  |  |  |
| Belgium | 94 | 1971 | 88 | 10 | 11 |
| (Flemish only) | 95 | 1975-76 | 87 | 8 | 9 |
| Bulgaria | 301 | 1976 | 76 | 2 | 3 |
| Canada | 80 | 1976 | 62 | 5 | 8 |
| Czechoslovakia | 458 | 1970 | 66[c] | 13 | 19 |
|  | 301 | 1977 | 95 | 13 | 14 |
| Denmark[d] | 458 | 1970 | 67[c] | 20 | 30 |
|  | 405 | 1975 | 75[c] | 29 | 39 |
| Finland | 458 | 1971 | 77[c] | 31 | 40 |
|  | 388 | 1977 | 75[c] | 32 | 43 |
| France | 458 | 1972 | 64[c] | 8 | 12 |
|  | 296 | 1978 | 88 | 7 | 8 |
| Hungary | 218 | 1977 | 73 | 4 | 6 |
| Italy | 130 | 1976-77 | 77[c] | 16 | 21 |
|  | 301 | 1979 | 78 | 13 | 17 |
| Japan | 459 | 1974 | 67[c] | 50 | 75 |
| Netherlands | 295, 328 | 1975 | 66[c] | 10 | 15 |
| Norway | 295,343 | 1977 | 71[c] | 15 | 21 |
| Poland | 458 | 1972 | 57[c] | 10 | 17 |
|  | 301 | 1977 | 75 | 14 | 19 |
| Romania | 459 | 1978 | 57[c] | 3 | 5 |
| Spain | 430 | 1977 | 50 | 5 | 19 |
| UK (England & Wales) | 71 | 1970 | 79[c] | 31 | 39 |
|  | 126 | 1976 | 86 | 22 | 26 |
| US | 458 | 1970 | 65[c] | 9 | 14 |
|  | 144 | 1973 | 70 | 9 | 14 |
|  | 330 | 1976 | 68 | 7 | 11 |
| Yugoslavia | 301 | 1976 | 58 | 2 | 4 |

Note: Data from Contraceptive Prevalence Surveys (106, 329, 391) except Bangladesh (53) exclude douche, abstinence, and "other" from total contraceptive users; data from World Fertility Survey (81, 86, 179, 181, 257, 301, 454, 466) and Bangladesh Contraceptive Prevalence Survey (53) include these methods.

Note: Women surveyed are currently in union (Latin America & Caribbean) or married (elsewhere), age 15-44 or 15-49. Exceptions are: **AFRICA: Lesotho**, fecund, nonpregnant; **Mauritius**, ever-married, age <50; **Senegal**, fecund, nonpregnant; **Sudan** (North), fecund, nonpregnant; **LATIN AMERICA & CARIBBEAN: Barbados** 1971, all women, age 15-45; **Costa Rica** 1976, age 20-44; **Haiti**, fecund, nonpregnant; **Panama** 1976, age 20-44; **Puerto Rico**, ever-married; **Trinidad & Tobago** 1970, ever in union; **Trinidad & Tobago** 1977, in union, fecund, nonpregnant; **Venezuela**, in union, fecund, nonpregnant; **MIDDLE EAST & NORTH AFRICA: Syria** 1978, fecund, nonpregnant; **Turkey**, fecund, nonpregnant; **DEVELOPED COUNTRIES: Belgium** 1971, age 30-34; **Belgium** 1975-76, age 16-44; **Bulgaria**, fecund, nonpregnant, in first marriage, age <45; **Canada**, all women; **Czechoslovakia** 1970, age <50; **Czechoslovakia** 1977, fecund, nonpregnant, in first marriage, age <45; **Denmark** 1970, age 18-49; **Denmark** 1975, age 18-49; **Finland** 1971, age 18-54; **Finland** 1977, in first marriage, age 18-54; **France** 1972, ever-married, age <45; **France** 1978, fecund, age 20-44; **Hungary**, age <40; **Italy** 1976-77, all women, age 18-64; **Italy** 1979, fecund, nonpregnant, in first marriage, age <45; **Netherlands**, married continuously since 1963-1973, all ages; **Norway**, fecund, nonpregnant, age 18-44; **Poland** 1972, age <50; **Poland** 1977, fecund nonpregnant, in first marriage, age <45; **Romania**, in first marriage; **Spain**, fecund, nonpregnant; **UK** 1970, fecund, nonpregnant, ever-married, age 16-40; **US** 1970, ever-married, age <45; **Yugoslavia**, fecund, nonpregnant, in first marriage, age <45.

[a] Figures are not derivable from preceding columns due to rounding.

[b] Pakistan—Respondents were asked about use only after they spontaneously mentioned method in knowledge section of survey.

[c] Excludes sterilization. All others include users of voluntary sterilization.

[d] Denmark—Excludes central municipalities of Copenhagen

Geographic differences in condom use are striking (see Table 1 and Figure 2). Japan alone accounts for more than one-fourth of the condom users in the world. The developed nations as a whole, including Japan, account for almost two-thirds of worldwide condom use. With the addition of China, over 80 percent of condom use is accounted for. In the rest of Asia and in Latin America, the Caribbean, Africa, and the Middle East—areas of relatively high fertility and relatively little contraception—condom use is limited and disproportionately low compared with other methods (81, 329).

In all developed countries for which survey data are available, except Eastern European countries, at least 5 percent of married women of reproductive age rely on condoms (see Table 2). In 11 of these countries at least 10 percent of contraceptive users are relying on condoms. Measured as the percentage of all contraceptors, condom use is highest in Japan, at 75 percent, and in Denmark and Finland, at about 40 percent. It is lowest in Bulgaria, Hungary, Romania, and Yugoslavia. According to nationally representative sample surveys taken during the past decade, condom use, measured both as a percentage of married women of reproductive age and as a percentage of contraceptors, has increased in some developed countries, including Denmark and Finland, and decreased in others, including Czechoslovakia, Italy, the United Kingdom, and the United States. Steady increases in condom use have occurred in Japan (282).

By contrast, in only 12 of 47 developing areas with survey data do at least 5 percent of married women of reproductive age rely on condoms. These are mostly small countries and include Mauritius, Fiji, Hong Kong, South Korea, Singapore, Barbados, Costa Rica, Guadeloupe, Jamaica, Martinique, Trinidad and Tobago, and Venezuela. In only 14 areas do at least 10 percent of contraceptors use condoms (see Table 2).

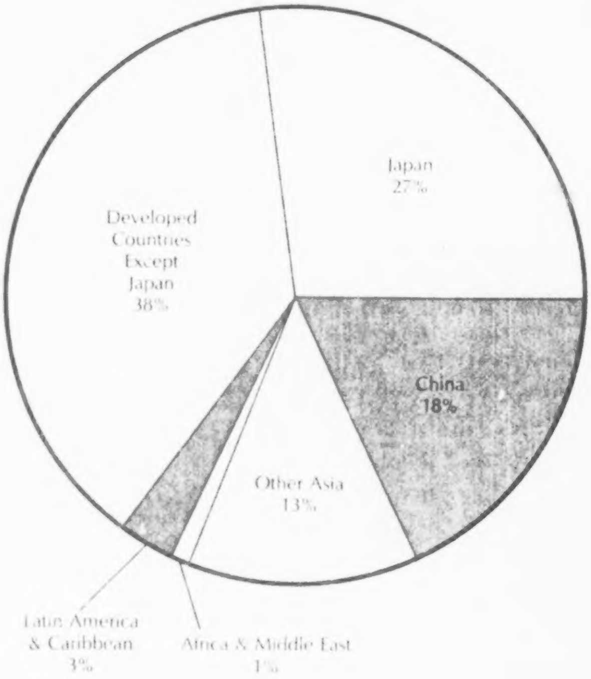
In most developing countries for which there are sequential survey data, the percentage of condom users has remained stable over time. Condom use doubled in Trinidad and Tobago, however, from 9 percent of all couples in 1970 to 18 percent in 1977, and increased slightly in Singapore and Thailand. In Bangladesh, condom use rose from one percent to two percent of all married couples between 1975 and 1979 (see Table 2).

The percentage of all contraceptors who use condoms has decreased in some developing countries as other contraceptive methods have become more widely available. Among contracepting couples, the percentage using condoms decreased by at least six percentage points in South Korea, Barbados, and Jamaica (see Table 2).

As with all contraceptive methods, condom use tends to be greater in urban than in rural areas of developing countries (39, 40, 41, 104, 212, 270, 282, 317, 332, 338, 365, 391). This difference may be greater for condoms than for some other contraceptives because the retail outlets that are the main source of condoms are concentrated in urban areas.

In addition, in 10 of 17 developing countries, condom use is greater among women who desire more births than among those who desire no more births. These include Bangladesh (55), Colombia (97), Guyana (178), Jamaica (245), South Korea (274), Panama (349), the Philippines (363), Sri Lanka (432), Thailand (89), and Trinidad and Tobago (454). In other words, in many countries condoms, like oral contraceptives, are used more often as a means for spacing births than for limiting births.

**Figure 2. Percentage of Condom Users in Areas of the World, 1981**



Condoms are often used in combination or alternation with various fertility awareness techniques or Natural Family Planning methods (see **Population Reports**, *Periodic Abstinence: How Well Do New Approaches Work?*, I-3, September 1981). In alternate use, which is more common, no method is used during infertile periods, and condoms are used during the period identified as fertile (96). In Japan, where the condom is the most widely used contraceptive and periodic abstinence is the second most widely used, it is estimated that combined or alternate use accounts for 19 to 46 percent of condom use (96). Combined or alternate use is very common in South Korea (270) and is also reported in the Philippines (286), Sri Lanka (219), and Poland (318). No doubt the practice is known worldwide.

## DISTRIBUTION

There are at least four ways that condoms reach users:

- through established commercial channels,
- through family planning clinics or physicians,
- through community-based distribution (CBD) or household distribution projects,
- through social marketing programs.

Established commercial channels supply the majority of condom users around the world. In most developed countries condoms are readily available through retail outlets—most often pharmacies but also barber shops, tobacconists, mail order houses, and vending machines. Vending machines are common in some European countries. They allow anonymous purchase, are always available, and can be inexpensive to maintain (415). In West Germany, for instance, it has been reported that 50 percent of condom sales are through vending machines (112).

Commercial channels also play an important role in developing countries. In countries without extensive family planning programs or where these programs do not promote condom use, retail outlets may be the only places to obtain condoms. For instance, in Nigeria, Ghana, and Uganda, almost all condoms are bought on the commercial market (68). In Colombia, South Korea, Mexico, and São Paulo State, Brazil, at least two-thirds of condom users buy condoms from a private source, usually a pharmacy (104, 338). In Costa Rica, Guatemala, and Thailand, about half of users buy condoms from a pharmacy (104, 365).

In many developing countries the cost of condoms makes it difficult for all but upper-income couples to buy them regularly. Imported condoms often are subject to high tariffs and duties—as much as 67 percent in Turkey (477). In addition, commercial markups from importer through distributor and wholesaler to retailer often total over 100 percent of the importer's cost. In Venezuela in 1972 a condom cost $0.23 (US). A yearly supply, estimated at 120 condoms, would have cost 2.5 percent of the average per capita income—far more than most couples would be willing to pay (477).

Condoms also reach the commercial market illegally. In Turkey, for instance, where supplies were not sufficient to meet demand in the late 1970s, condoms were smuggled into the country and sold at whatever price people were willing to pay (78).

### Clinics and Health Programs

Family planning clinics or physicians sometimes distribute condoms, but they are rarely a major source of supply. Most clients of maternal and child care or family planning clinics are women. Also, condoms are not considered a "medical method" and so sometimes are not actively promoted by clinic staff or physicians. For instance, in Britain, where contraceptives are supposed to be supplied free as part of the National Health Pro-

## CONDOM USE IN JAPAN

The availability of an ultra-thin, virtually flawless condom, widespread, imaginative marketing, and limited availability of other contraceptive methods have made the Japanese the world's major users of condoms (315, 332). In 1974 it was estimated that half of Japanese women of reproductive age relied on condoms (459), and in 1977 an estimated 79 percent of contracepting couples relied on condoms (332).

In the mid-1950s the Japanese Family Planning Association encouraged condom use as an alternative to induced abortion—the most common means of avoiding unwanted births in the years just after World War II (252, 332, 441, 457). Condom production and use rose steadily throughout the 1950s and early 1960s (277), and between 1962 and 1972 annual sales rose from 1.7 to 4.3 million gross (277). This may have been due to the increase in the marriageable population and the tendency toward younger marriage as well as to an increasing proportion of couples using condoms (277).

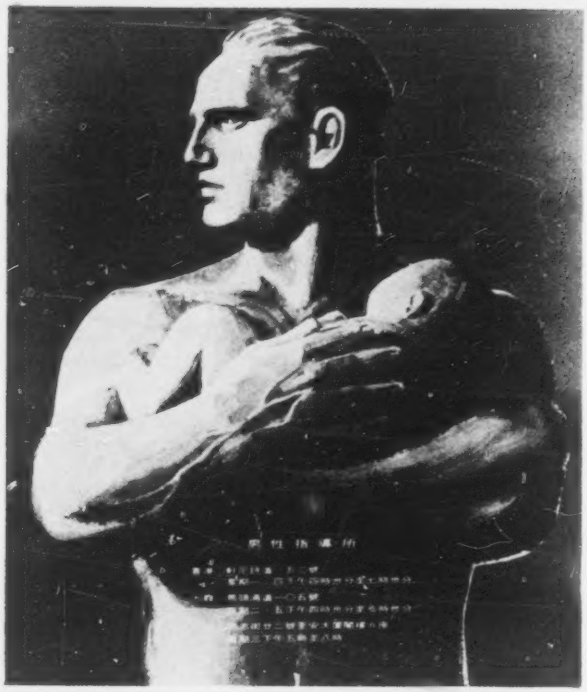
The increased use of condoms also is attributed to innovations in condom production and marketing:

- form-fitting condoms (1963),
- door-to-door sales to housewives by saleswomen (1967),
- condoms with new shapes and textures (1969),
- ultra-thin condoms, which are about half as thick as those available previously (1970) (156, 277).

Perhaps the most important of these innovations were the introduction of the thin condom and door-to-door sales. When thinner condoms were introduced, sales increased by over one million gross, or 43 percent, in one year (277). Segmenting of the market, with men buying condoms from salesmen in pharmacies and women buying condoms from saleswomen in their homes, as well as in pharmacies, also has been very successful. It is estimated that as many as 20 percent of all condom sales are to housewives in their homes (275, 373). Condoms also are sold in the larger supermarkets beside feminine napkins and tampons and from vending machines in places where the machines can be watched (332, 457).

All of these advances were accompanied by improvements in advertising, promotion, and packaging. Larger packages, containing 25, 50, or even 100 individually sealed condoms, were introduced for sales both in stores and door-to-door (277). Disposal bags, cleaning towlettes, finger sacks, instruction sheets, and reordering cards are now included in some packages. The sophisticated packaging, imaginatively designed by leading commercial artists (315), resembles other household items, presumably to avoid embarrassment at the point of purchase (457). Condom packages look like boxes of expensive cigars or cosmetics, for example. Commercial condom promotion now emphasizes the enjoyable aspects of condom use as well as their importance in birth and disease control (315, 332). Names such as *Yearn, Dream Special, Paradise,* and *Lady Wet* suggest the erotic pleasures of condoms. In addition to strictly commercial efforts, public health workers and midwives also promote the use of condoms (332, 457). In rural areas some customers are reached systematically through circulation of the *Ai no kobako* (the Love Box), which contains condoms and a sealed piggy bank so that condom users can buy their supplies discreetly and without embarassment (10, 332).

Another factor contributing to the widespread use of condoms in Japan is that other contraceptive methods have been either unavailable or unacceptable. The pill is not legal for contraception. Recent sales data suggest that less than one percent of women of reproductive age are using oral contraceptives regularly (273). IUDs also are little used. In 1974 only 5 percent of married women of reproductive age used IUDs (459). The low levels of IUD use may be because the devices are relatively expensive, because physicians insist that they be replaced every one or two years, or because many Japanese women object to having a foreign object in the uterus (96, 457). Voluntary sterilization in Japan is legally restricted to eugenic and therapeutic reasons (436) and is relatively uncommon (457). Spermicides and diaphragms have been unpopular, apparently because Japanese women know little about them and are reluctant to use methods that require them to handle their genitals (96). The only other contraceptive methods used extensively are methods to determine the woman's fertile period, which are often combined with condom use (96). Induced abortion is still commonly used to terminate pregnancies following contraceptive failures (282).



**Emphasizing male responsibility for family planning may encourage condom use. In 1975 the Family Planning Association of Hong Kong issued this poster and in 1977 started a "Mister Family Planning" campaign using television and comic strips.** (FPAHK)

gram, some family planning clinics nonetheless require that men buy condoms at pharmacies (211).

An exception is Singapore, where, through the extensive network of government Maternal and Child Health/Family Planning clinics, 36 percent of women choosing a contraceptive between 1966 and 1975 chose condoms (253). In 1980 more new acceptors chose condoms than oral contraceptives—61 percent compared with 37 percent (500). Part of this success is probably due to extensive information and education campaigns (305).

The Family Planning Association of Hong Kong (FPAHK) also has carried on vigorous promotions. In 1977 the Association launched a "Mr. Family Planning" campaign that promoted male responsibility and condom use (see photos, this page). In addition, the Association installed condom vending machines in men's public toilets (288). The percentage of FPAHK clients using condoms rose from 25 percent to 30 percent between 1977 and 1981 (288). Another male responsibility campaign was launched in 1982 (495).

### Community-Based Distribution

Condoms also have been distributed through community- or household-based family planning programs, but with limited success. Community-based distribution (CBD) programs offer contraceptives free or at a nominal charge through town depots or house-to-house visits. Most, however, do not advertise or otherwise promote their products. Local women, usually volunteers, often are used to recruit villagers and supply them with contraceptives. In South Korea, a 3-year program beginning in 1976 used local canvassers to provide women with free oral contraceptives or condoms and to explain about resupply and procedures for sterilization and IUD insertion. Overall, contraceptive prevalence increased by 14.5 percent, but condom use increased by only 1.3 percent (183). In Thailand the Community-Based Family Planning Services (CBFPS) village program recruits a respected person in each village to promote and distribute OCs and condoms. A subsidized price of about $.04 (US) per condom is charged. Villagers have been much less interested in condoms than in OCs and generally think of condoms only as a supplementary method (98, 468).

In another South Korean project, nominally priced OCs and condoms priced at $.05 (US) were distributed through Mothers' Clubs, government centers, and commercial outlets. Use of the condom, called *Coatseen*, increased, although mainly at the expense of condoms available through the private sector (183, 367). In Bangladesh a special condom distribution program delivered condoms to 35 percent of eligible households in Matlab Thana. Usage increased from 1.2 to 4.8 percent (214, 383). In Nepal a survey of potential social marketing customers distributed *Dhaal* condoms free to almost 5,000 households and provided information about resupply. Follow-up interviews four months later showed that between 40 and 70 percent of condom acceptors in various regions tried the method. Only 9 percent of these bought more condoms. The percentage who knew where to obtain condoms rose from 10 to 40 percent, however (476).

An Indonesian study found that villagers who were resupplied with OCs, condoms, or foam through village depots were "more likely to be consistent contraceptors" than those who were re-

男用避孕套
自動售賣機
Condom Vending Machine
2x1$
wait coins to drop
pull handle out
push back firmly

**Vending machines can provide condoms to men who prefer to buy them anonymously or who need supplies when shops are closed. In Hong Kong, the Family Planning Association has installed condom vending machines in men's public toilets.** (FPAHK) supplied through clinics (447). Responses to about 1,500 questionnaires collected in 1975 and 1976 indicated that village-level resupply, mainly of OCs, resulted in a 24-month continuation rate of 61 percent compared with 48 percent for clinic resupply. These results suggest the obvious conclusion: that men and women who have already accepted a method which must be regularly supplied are more likely to continue using it when it is locally available (446, 447).

CBD programs often have difficulty training, motivating, and retaining local distributors or canvassers (183, 214, 324, 351, 468). The cost of setting up an entirely new distribution system tends to be high, and CBD programs, like clinic-based health programs, are usually oriented toward women's concerns and contraceptive methods.

### Social Marketing

Social marketing programs seek to combine the best of various approaches—low cost to the consumer, as in clinic and CBD programs, and widespread availability, as in commercial retail distribution. These programs use established commercial channels to distribute family planning and health products at a subsidized price (298, 306, 309) (see **Population Reports**, *Social Marketing: Does It Work?*, J-21, January 1980). Condoms are an ideal product for social marketing since they do not require medical advice, must be regularly supplied, and are easy to transport (222). Promotion and advertising generally follow commercial models, attempting to increase awareness and create a favorable image for the product (196, 298, 309). In the last decade a number of developing countries have started social marketing programs either for condoms alone or in combination with OCs or contraceptive foam. These countries include India, Bangladesh, Sri Lanka, Nepal, Jamaica, Mexico, Colombia, El Salvador, Egypt, and Ghana (see Table 3). In Thailand also, CBFPS includes elements of a social marketing program, particularly the condom sales in urban areas.

The brand names and packaging designs chosen for social marketing products are intended to be culturally appropriate

**Table 3. Major Condom Social Marketing Programs**

| Region, Country & Year Started | Ref. No. | Management | Brand Name and Price in $US per Condom* | Other Products Sold in Program (with Brand Names) | Further Description |
|---|---|---|---|---|---|
| **ASIA** | | | | | |
| **Bangladesh 1975** | 4, 32, 53, 54, 91, 205, 306 | Population Services International (PSI) | Raja $.008 | OC (Maya, Ovacon)<br>Vaginal tablet (Joy) | Donated condoms repackaged locally.<br>Program has own salesmen and distributors. Extensive mass-media advertising emphasizing health, happiness, financial security.<br>In 1979, 32% of all condom users used *Raja*; in 1981, 41%.<br>Condom sales greater than OC sales. |
| **India 1969** | 17, 147, 281, 438 | Government of India Ministry of Health and Family Welfare | Nirodh $.03 | None | Condoms manufactured in Indian plants.<br>Cost/CYP $1.67, including cost of condoms, in late 1970s.<br>Local distribution through a number of large companies. $500,000/year spent on advertising.<br>1974–1975 drop in sales coincided with less promotion and higher price.<br>Success of program varies among states. |
| **Nepal 1978** | 205, 416, 417, 474 | Government of Nepal Family Planning and Maternal and Child Health Program and Westinghouse Health Systems | Dhaal $.013<br>Suki Dhaal $.010 | OC (Gulaf) | Donated condoms repackaged locally.<br>Own sales force sells directly to distributors.<br>Advertising stresses economic benefits. Radio spots not permitted to mention product name.<br>Suki Dhaal, plain condom in less expensive package, recently introduced for rural markets.<br>Condom sales greater than OC sales. |
| **Sri Lanka 1973** | 23, 113, 132, 185, 306, 474 | Family Planning Association of Sri Lanka | Preethi $.016 | OC (Mithuri, Norinyl)<br>Vaginal tablet (Neo Sampoon) | Condoms purchased with donated funds.<br>Cost/acceptor $2.16, cost/CYP $6.19, including cost of condoms, in 1974.<br>Distribution through major household products company.<br>Advertising through newspaper, cinema, bus cards, POP displays.<br>Radio ads banned 1973–76.<br>Condom sales greater than OC sales. |
| **Thailand 1974** | 76, 78, 453, 478 | Community-Based Family Planning Services (CBFPS) | Special Mechai<br>Mechai Rainbow<br>Mechai Skinless Skin<br>Mechai Supreme<br>Mechai Black Superman<br>$.07 | OC (Eugynon, Norinyl, Ovostat) | Donated condoms sold through rural CBD and urban private-sector programs.<br>No commercial advertising. POP promotion and media converage of Mechai Viravaidya's promotional schemes.<br>Condoms more popular in urban than in rural areas. |

and attractive. In Bangladesh the name *Raja* was chosen for the condom brand because of its easily recognized symbol—the king of spades—and its masculine image (188). In El Salvador the name *Condor* was chosen for the same reasons. A small-scale Indonesian program marketed condoms under the name *Karet KB*, which means "family planning rubber," in order to stress that condoms can be used by married couples rather than just by men engaging in nonmarital sex (78). In Egypt some have blamed the slow sales increases for *Tops* condoms on the Western-sounding name (372, 455).

One of the biggest advantages of social marketing programs is that they can distribute condoms and oral contraceptives throughout a country by using established distribution and retailing networks. In Colombia, for example, the Profamilia social marketing program distributes condoms through wholesalers of cosmetics and toiletries (15). As a result of this partnership, condoms are now available in about 2,000 pharmacies and several supermarkets through the social marketing program as well as in clinics and community depots throughout the

**In Nepal the social marketing program sells *Dhaal* condoms with a new image—spacing children responsibly. This poster, designed by an advertising firm, reads, "When do you want the next baby? When this one is grown up! Please use *Dhaal* between now and then."** (Westinghouse Health Systems/Commat)

**Table 3 (Continued)**

| Region, Country & Year Started | Ref. No. | Management | Brand Name and Price in $US per Condom* | Other Products Sold in Program (with Brand Names) | Further Description |
|---|---|---|---|---|---|
| **LATIN AMERICA & CARIBBEAN** | | | | | |
| **Colombia 1973** | 369, 396 | Profamilia | Tahiti<br>Prime<br>Stimula } $.07–.10 | OC (Noriday: Schering AG, Wyeth brands)<br>Vaginal tablet (Neo Sampoon)<br>Suppository (Norforms) | Condoms purchased directly from Ansell Inc. and Ansell condoms obtained from donors are resold without repackaging.<br>Limited press advertisements and POP displays.<br>Sales help support CBD and clinic programs. |
| **El Salvador 1978** | 114, 116, 205 | Asociación Demográphica Salvadoreña | Condor $.045 | OC (Perla) | Donated condoms repackaged locally.<br>Distribution through local pharmaceutical distributor.<br>Advertising suspended for part of 1978 due to political unrest.<br>OC sales greater than condom sales. |
| **Jamaica 1975** | 205, 399, 475 | Jamaica National Family Planning Board | Panther $.10 | OC (Perle) | Donated condoms repackaged locally.<br>Cost/acceptor = $2.62 in 1979.<br>Distribution through largest local food distributor.<br>OC sales greater than condom sales. |
| **Mexico 1979** | 26, 309, 474 | Protam | Profam<br>Alazan<br>Selecto 3<br>Super Macho } $.17 (1981) | OC<br>Vaginal cream, foam, suppository (all Protam) | Condoms donated to program until 1981.<br>Extensive advertising and promotion until 1981. House-to-house promotion and sample distribution. Training program for retailers.<br>Government support ended in 1981.<br>Condom sales greater than OC sales. |
| **MIDDLE EAST** | | | | | |
| **Egypt 1979** | 121, 205, 212 | Family of the Future/ Triton Corporation | Tops $.031 | Vaginal tablet (Amaan)<br>IUD (TCu-200, Cu-7) | Problem maintaining consistent supply in early stages.<br>Mainly newspaper advertising. Volunteers organize promotional and instructional rallies. Samples handed out at festivals.<br>IUD sales (by pharmacies and physicians) greater than condom sales. |

*1982 price unless stated otherwise

OC = oral contraceptives CYP = couple-years of protection POP = point-of-purchase CBD = community-based distribution

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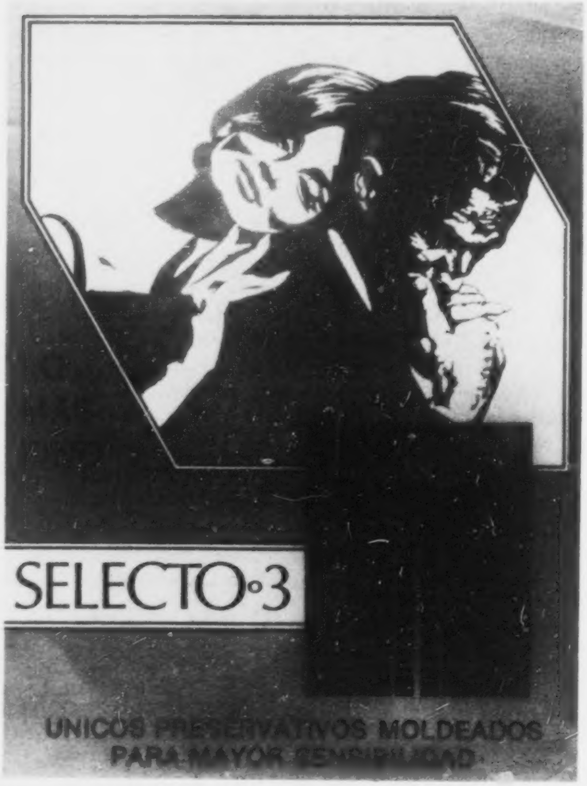
country (369). In India a variety of major companies distribute *Nirodh* condoms, including Brooke Bond, Lipton, Union Carbide, and Hindustan Petroleum (16). In El Salvador *Condor* condoms are distributed by a pharmaceutical distributing company (116). In Indonesia a traditional medicine company, Jamu Cap Djago, distributed *Karet KB* from village to village in Java and Bali (1, 203).

Some social marketing programs have established their own distribution networks or hired salesmen to recruit wholesalers or retailers directly. In urban areas of Thailand CBFPS uses a variety of distributors. In Bangkok, for instance, CBFPS has 200 distributors of condoms in factories and 100 in slum areas. Also, over 250 taxi drivers sell condoms from their cars (453). In rural areas village representatives sell condoms and keep $.05 (US) for every five sold (442). In Bangladesh, where other distribution networks proved less reliable, the *Raja* program employed its own area managers and salesmen to work with wholesalers and distributors.

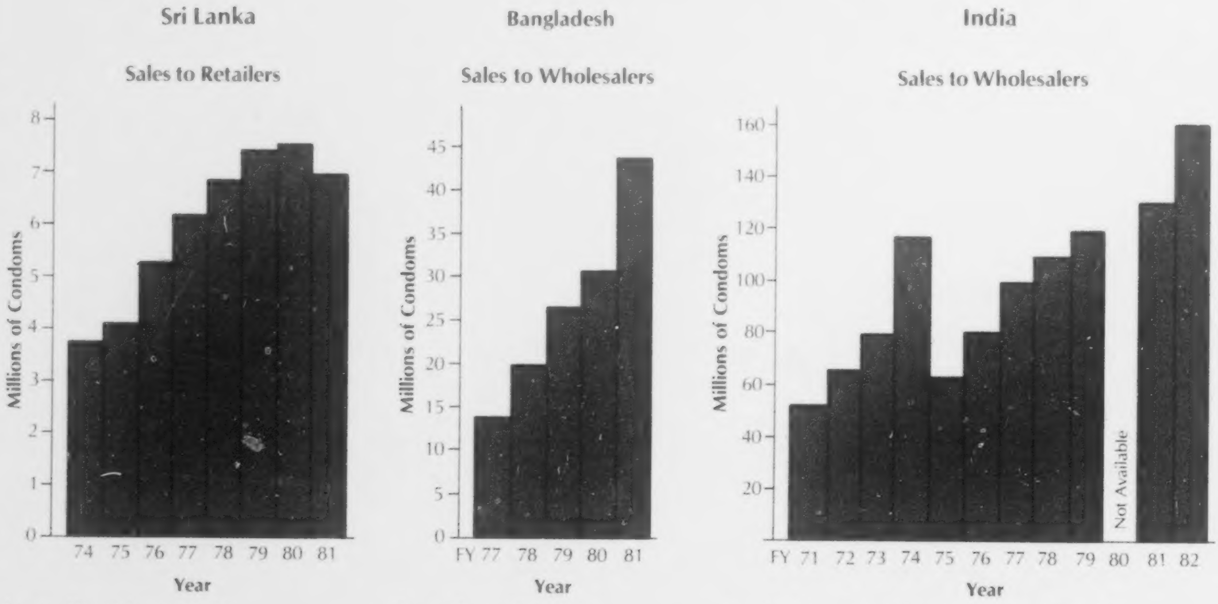
Two other strategies have been tried to increase the availability of subsidized condoms—mail-order programs and vending machine sales. These could eliminate some steps on the distribution ladder (415), and they offer complete privacy to buyers. In fact, however, they have proved difficult to sustain. Obviously, mail-order programs are limited to areas where people are literate and where reliable postal services exist. Also, use of the mails can be abused. In Sri Lanka a mail order program for *Preethi* initiated in the mid-1970s was halted after pranksters began sending condoms to young, unmarried girls and community leaders (172).

Some family planning programs and social marketing projects have tried selling condoms at subsidized prices from vending machines. They have encountered numerous problems. These include vandalism, machine breakdowns, and rejection of the light-weight coins in common use (373, 400, 412). In Bogotá, Colombia, the contents of machines were stolen and then resold on the street (15). Vending machines have been very successful in some locations, however. For instance, in El Salvador, Colombia, and Bangladesh, machines in bus terminals and cinema lobbies sold large numbers of condoms—as



**This poster from the Mexican Profam social marketing program emphasizes sophistication and wealth. *Selecto 3*, one of four condom brands sold by Profam, is advertised as "the finest ... selected, molded condoms for maximum sensitivity."** (Courtesy of Profam)

**Figure 3. Sales of Condoms by Established Social Marketing Programs in Asia, by Year**



Source: Abeywickrema (23, 24)

Source: Futures Group (162)

Source: Gupta (177), Jain (244), Kumar (280), Smith (425)

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many as 16 gross per month from one Colombian machine (314). In general, however, vending machines have supplied only a very small proportion of condom users, and only in urban areas.

### Success of Social Marketing

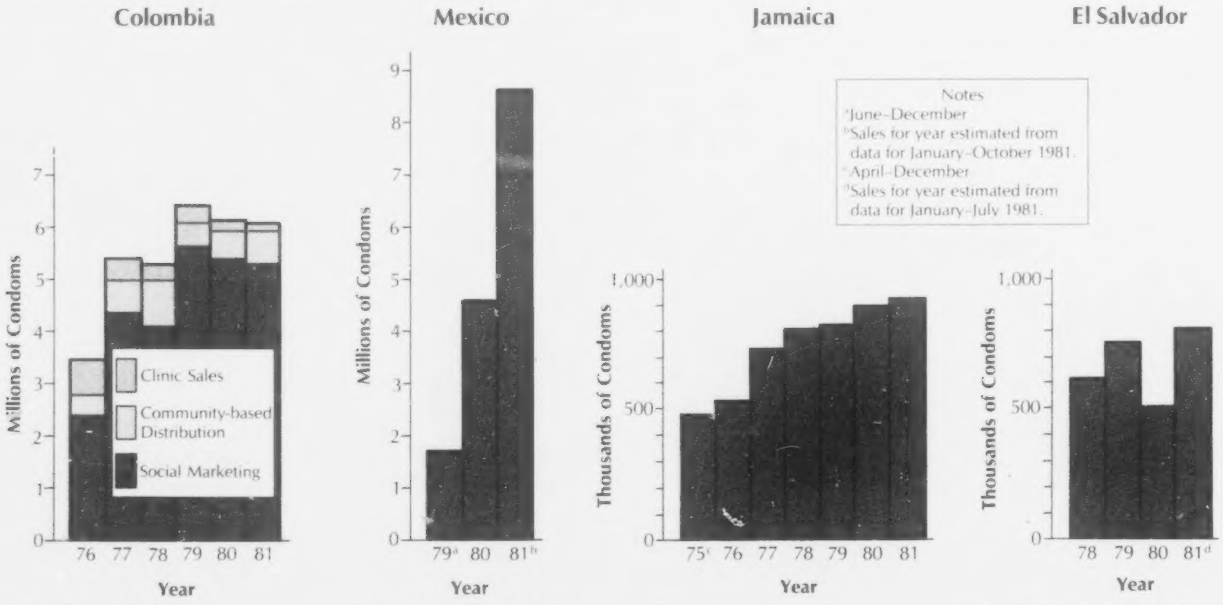
How successful are social marketing programs in increasing availability and usage of condoms? Where condoms have been introduced through social marketing programs, sales tend to increase rapidly at first (382) (see Figures 3-5). The Sri Lankan social marketing program began in 1973 and by 1976 sold 5.2 million in a year (113) (see Figure 3). Sri Lanka is an ideal country for a marketing program because it is small, has good transportation systems, and has a high literacy rate (172). Although marketing is much more difficult in India than in Sri Lanka, sales in the Indian *Nirodh* program rose fast from about 50 million in 1970-71 to over 115 million by 1973-74 (35) (see Figure 3). Subsidized condom sales also have risen sharply in the young programs of Bangladesh and Mexico (see Figures 3 and 4). Overall, by conservative calculations, condoms sold in social marketing programs currently provide protection against pregnancy to between 0.5 percent of married women of reproductive age in Egypt and Nepal and 8 percent in Jamaica (see Figure 6).

While sales rise sharply for the first few years in many social marketing programs, in older, established programs—such as in India, Sri Lanka, and Jamaica—sales growth has eventually slowed. This might be expected as more and more potential customers are reached. It also may be due partly to reduced advertising and promotion compared with the intense campaigns used to introduce new programs. Other factors that can slow sales increases are political instability—as in the case of El Salvador—and increases in prices designed to make programs more self-supporting—as in India in 1974 (35). Higher prices may have discouraged some potential customers or caused retailers to delay purchasing new stock from wholesalers.

In all programs, sales have grown. But how many of these sales are to new users, and how many to continuing users who switch from regular commercial products to the cheaper, more readily available social marketing brands? In some countries, such as Bangladesh, condoms were not readily available through the private sector before social marketing began. Thus, it can be assumed that in these countries almost all sales are to new users. In countries where condoms are readily available through commercial channels, however, use of socially marketed condoms may replace use of other condoms to some extent. In Sri Lanka, when the *Preethi* program began in 1973, regular commercial distribution to retail outlets declined from 500,000 in 1972 to 130,000 in 1973 (35). Social marketing sales were far greater than the previous commercial sales, however—about 3.7 million in 1974, the first full year (162). In Jamaica social marketing did not have as great an effect on other condom sales. In 1975 almost 500,000 condoms were sold by the private sector. In 1977, 450,000 commercial-brand condoms were sold in addition to about 750,000 subsidized *Panther* condoms (162, 475).

A major advantage of social marketing programs is that they are relatively inexpensive to operate, especially after the first few years. The Indian *Nirodh* program had a cost of $2.51 (US) per couple-year of protection (CYP) in 1970-71 and $1.67 per CYP in 1978-79, including the cost of condoms provided by Indian manufacturers (35). The Bangladesh program had costs of $5.65 per CYP in 1976 and $4.63 in 1978 for both condom and OC sales. Excluding the costs of contraceptives, the 1978 cost was $1.44 per CYP (35, 306). In Thailand the CBFPS village program, which includes elements of both a community-based and a social marketing program, had a cost per CYP of $7.87 in 1980, excluding cost of condoms, OCs, and foam (88). In Sri Lanka the *Preethi* program cost $6.19 per CYP in 1974, the first year of operation. The cost per acceptor was $2.16 (305). Sri Lanka data include the cost of condoms provided by the International Planned Parenthood Federation (IPPF). In Jamaica the cost per acceptor of *Panther* condoms was $2.62 in 1979 (399). These costs compare favorably with the costs of noncommer-

**Figure 4. Sales of Condoms to Consumers by Social Marketing Programs in Latin America and the Caribbean, by Year**



Notes
ᵃJune-December
ᵇSales for year estimated from data for January-October 1981.
ᶜApril-December
ᵈSales for year estimated from data for January-July 1981.

Source: Samuel (397, 398)

Source: Futures Group (162)

Source: Futures Group (162)

Source: Futures Group (162)

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cial, community-based distribution programs—about $23 per acceptor in South Korea, for example (351).

### Donor Agency Supply

Most social marketing programs, family planning clinics, and community-based distribution projects distribute condoms donated by various agencies. Many of these are supplied by the United States Agency for International Development (USAID), the largest donor over the past seven years. Donations of condoms by USAID peaked in 1975 and have averaged over one million gross per year since that time (see Table 4). Three Asian countries received the largest quantities from USAID between 1975 and 1981. They were Bangladesh (2.9 million gross), Pakistan (2.5 million gross), and the Philippines (640,000 gross). Countries receiving between 200,000 and 400,000 gross were Egypt, Haiti, and Jamaica (70, 382).

Condoms also are provided with USAID assistance through private organizations such as Family Planning International Assistance (FPIA), the International Planned Parenthood Federation (IPPF), and the Pathfinder Fund. Since 1975 FPIA has donated an average of 600,000 gross per year. Recipients of the largest quantities between 1975 and 1981 were the Philippines (one million gross), Bangladesh (900,000 gross), and Mexico (500,000 gross) (175, 382). IPPF recently has supplied an average of 250,000 gross per year to affiliated family planning associations. Since 1975 IPPF has provided Sri Lanka with 400,000 gross and Colombia with 285,000 gross (77, 382). The Pathfinder Fund has donated an average of 125,000 gross per year since 1975. Egypt received a total of 330,000 gross, and Mexico, almost 200,000 gross (125, 382).

Other national and international agencies also supply condoms for developing country programs. Since 1975 the United Nations Fund for Population Activities (UNFPA) has provided an average of 335,000 gross per year, with the largest quantities going to Pakistan, Indonesia, and Vietnam (51, 382). The Swedish International Development Authority (SIDA), the government of Japan, the UK Overseas Development Administration (ODA), and the Japanese Organization for International Cooperation in Family Planning (JOICFP) have supplied smaller quantities of condoms, primarily in Asia and the Pacific (119, 382, 485) (see Table 4).

Some developing countries provide their own condoms for family planning programs. In India the government buys condoms for its *Nirodh* social marketing program from Indian manufacturers. The South Korean Family Planning Association also provides locally manufactured condoms. In China, most of the condoms, which are distributed free of charge, are produced in four large plants (360). In Colombia the Profamilia social marketing program buys condoms directly from Ansell Incorporated (formerly Akwell Industries) in the US and uses the Ansell brand names. Ansell offers the program a low price since Profamilia acts as its sole distributor in Colombia (398). Profamilia also receives donated condoms from USAID for its clinic and CBD programs.

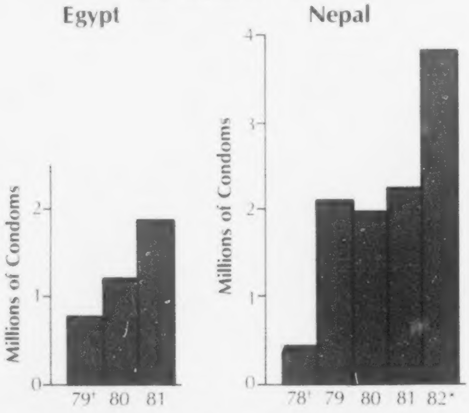
## MARKET RESEARCH AND PROMOTION

Whether condoms are distributed through a commercial, clinic-based, community-based, or social marketing scheme, identifying and understanding potential users is crucial. Knowing who users are and what they want enables suppliers to design packaging and promotion that will attract the most users.

In most countries promotion is aimed at men, since they usually are the ones who buy or collect supplies of condoms. Yet, although men have been taking an active part in family planning for decades (through condom use, coitus interruptus, and vasectomy), surprisingly little is known about male attitudes and preferences regarding contraception (138, 240, 438). Most surveys involve only women. Available data suggest that a majority of men in many countries approve of the idea of family planning. Thus they do not need to be convinced of the need for contraception. In Malaysia (47), South Korea (27), Chile (182), Peru (326), and the US (347), for instance, surveys of men have shown that most have positive attitudes toward birth control. In addition, the experience of social marketing programs suggests that, with encouragement and available supplies, many men will use a reliable method such as condoms.

In some countries effective condom promotion has been directed at women. As a result, women are playing an important

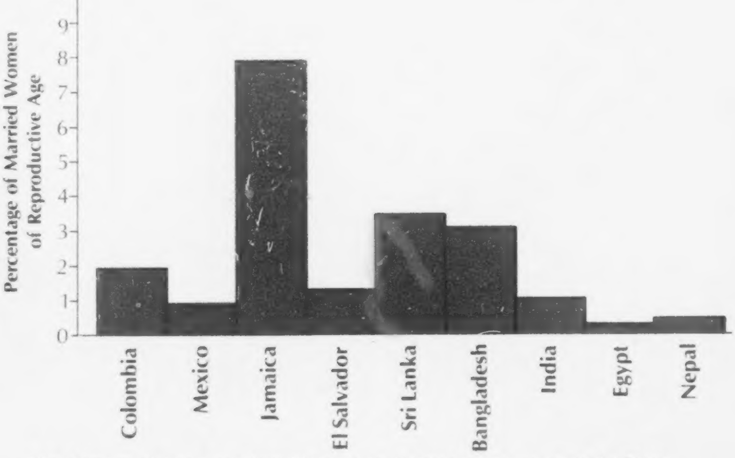
**Figure 5. Sales of Condoms to Consumers in the Social Marketing Programs of Egypt and Nepal, by Year**



†June–December
Source: Futures Group (162)

†June–December
*Sales for year estimated from data for January–June 1982.
Source: Futures Group (162)

**Figure 6. Estimated Percentage of Married Women of Reproductive Age Relying on Social Marketing Program Condoms* in Selected Developing Countries, 1981**



*Based on annual use per couple of 100 condoms. If annual use were estimated at 75 condoms, the percentages would be 25 percent higher.

role in obtaining supplies and in improving the image of condoms as an acceptable method for married couples. In South Korea, for instance, a survey of 735 couples who used or had used condoms revealed that in 37 percent of cases supplies were collected by women (270). In the US approximately one-third of condom purchasers are women (33). In Japan about 20 percent of all sales are to married women at home, and about half of all pharmacy sales are to women (96, 457). Japanese manufacturers have developed cosmetic-like packaging and brand names aimed at the female buyer (see box, p. H-134).

In developed countries new emphasis is being placed on the need to increase condom use among adolescents (62, 135, 250, 300, 406). Arguments for this emphasis include: (1) adolescents account for a high proportion of unmarried women giving birth and a high proportion of STD cases; (2) adolescents tend not to use contraceptive methods; (3) adolescents tend to have intercourse infrequently and so need contraceptive protection only occasionally. In the US an estimated 25 percent of gonorrhea cases, 30 percent of abortions, and 48 percent of out-of-wedlock births occur among 15- to 19-year-olds (135). In addition, a

**Table 4. Deliveries of Condoms by Donor Agencies, by Region and Year, 1975–1981**
(in gross)

| Region & Donor | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | Total |
|---|---|---|---|---|---|---|---|---|
| **AFRICA** | | | | | | | | |
| **USAID bilateral** | 39,010 | 32,050 | 1,000 | 17,097 | 15,917 | — | 583 | 105,657 |
| **FPIA**[a] | 47 | 8,830 | 8,261 | 11,882 | 9,552 | 13,119 | 20,889 | 72,580 |
| **IPPF** | 21,710 | 7,625 | 7,770 | 13,715 | 20,980 | 17,716 | 20,645 | 110,161 |
| **UNFPA**[b] | 7,000 | — | 3,350 | — | 5,279 | 8,922 | 3,893 | 28,444 |
| **Pathfinder** | 1,018 | 20,220 | 15,177 | 12,332 | 5,610 | 670 | 36,799 | 91,826 |
| **SIDA** | — | 1,600 | 1,000 | NA | NA | NA | NA | 2,600 |
| **Subtotal** | 68,785 | 70,325 | 36,558 | 55,026 | 57,338 | 40,427 | 82,809 | 411,268 |
| **ASIA & PACIFIC** | | | | | | | | |
| **USAID bilateral** | 2,053,485 | 1,866,120 | 1,092,437 | 371,338 | 436,083 | 258,583 | 515,292 | 6,593,338 |
| **FPIA**[a] | 18,136 | 309,866 | 757,541 | 543,065 | 450,368 | 286,892 | 414,809 | 2,780,677 |
| **IPPF** | 196,190 | 205,436 | 154,206 | 94,200 | 102,532 | 151,243 | 133,068 | 1,036,875 |
| **UNFPA**[b] | 1,620 | 494,208 | 57,628 | 100,000 | 687,542 | 751,277 | 117,809 | 2,210,084 |
| **Pathfinder** | 4,650 | 63,500 | — | — | — | 5,000 | — | 73,150 |
| **SIDA** | 30,000 | 30,000 | — | NA | NA | NA | NA | 60,000 |
| **Government of Japan** | 51,000 | 14,000 | 6,000 | 27,500 | 21,000 | 10,000 | 200 | 129,700 |
| **JOICFP** | — | — | — | — | 4,500 | 2,100 | 5,000 | 11,600 |
| **UK ODA** | NA | — | 135,000[a] | — | 1,700 | — | — | 136,700 |
| **Subtotal** | 2,355,081 | 2,983,130 | 2,202,812 | 1,136,103 | 1,703,725 | 1,465,095 | 1,186,178 | 13,032,124 |
| **LATIN AMERICA & CARIBBEAN** | | | | | | | | |
| **USAID bilateral** | 61,680 | 129,080 | 198,417 | 100,096 | 68,785 | 60,542 | 167,294 | 785,894 |
| **FPIA**[a] | 72,025 | 16,021 | 34,818 | 141,767 | 54,813 | 173,433 | 158,828 | 651,705 |
| **IPPF** | 89,435 | 37,210 | 85,775 | 61,982 | 67,569 | 117,400 | 76,217 | 535,588 |
| **UNFPA**[b] | — | 300 | 20,000 | — | — | 3,708 | 13,346 | 37,354 |
| **Pathfinder** | 37,620 | 56,875 | 11,605 | 17,162 | 5,558 | 185,874 | 56,747 | 371,441 |
| **SIDA** | — | — | — | NA | NA | NA | NA | NA |
| **Subtotal** | 260,760 | 239,486 | 350,615 | 321,007 | 196,725 | 540,957 | 472,432 | 2,381,982 |
| **MIDDLE EAST & NORTH AFRICA** | | | | | | | | |
| **USAID bilateral** | 31,120 | 39,760 | 65,000 | 200,000 | 150,000 | 6,958 | 6,958 | 499,796 |
| **FPIA**[a] | 52,019 | 47,875 | 80 | 2,424 | 71,757 | 271,564 | 240,215 | 685,934 |
| **IPPF** | 7,100 | 37,300 | 6,430 | 11,340 | 9,597 | 11,158 | 2,575 | 85,500 |
| **UNFPA**[b] | 39,910 | 30 | 25,780 | — | — | 12,250 | 2,875 | 80,845 |
| **Pathfinder** | — | 85,000 | 245,000 | 10,000 | — | — | — | 340,000 |
| **SIDA** | — | — | — | NA | NA | NA | NA | NA |
| **Subtotal** | 130,149 | 209,965 | 342,290 | 223,764 | 231,354 | 301,930 | 252,623 | 1,692,075 |
| **AGENCY TOTALS** | | | | | | | | |
| **USAID bilateral** | 2,185,295 | 2,067,010 | 1,356,854 | 688,531 | 670,785 | 326,083 | 690,127 | 7,984,685 |
| **FPIA**[a] | 142,227 | 382,592 | 800,700 | 699,138 | 586,490 | 745,008 | 834,741 | 4,190,896 |
| **IPPF** | 314,435 | 287,571 | 254,181 | 181,237 | 200,678 | 297,517 | 232,505 | 1,768,124 |
| **UNFPA**[b] | 48,530 | 494,538 | 106,758 | 100,000 | 692,821 | 776,157 | 137,923 | 2,356,727 |
| **Pathfinder** | 43,288 | 225,595 | 271,782 | 39,494 | 11,168 | 191,544 | 93,546 | 876,417 |
| **SIDA** | 30,000 | 31,600 | 1,000 | NA | NA | NA | NA | 62,600 |
| **Government of Japan** | 51,000 | 14,000 | 6,000 | 27,500 | 21,000 | 10,000 | 200 | 129,700 |
| **JOICFP** | — | — | — | — | 4,500 | 2,100 | 5,000 | 11,600 |
| **UK ODA** | NA | — | 135,000[a] | — | 1,700 | — | — | 136,700 |
| **TOTAL** | 2,814,775 | 3,502,906 | 2,932,275 | 1,735,900 | 2,189,142 | 2,348,409 | 1,994,042 | 17,517,449 |

NA = not available

Note: USAID bilateral aid is provided directly to national programs. Supplies purchased by USAID also are distributed by FPIA, IPPF, and Pathfinder.

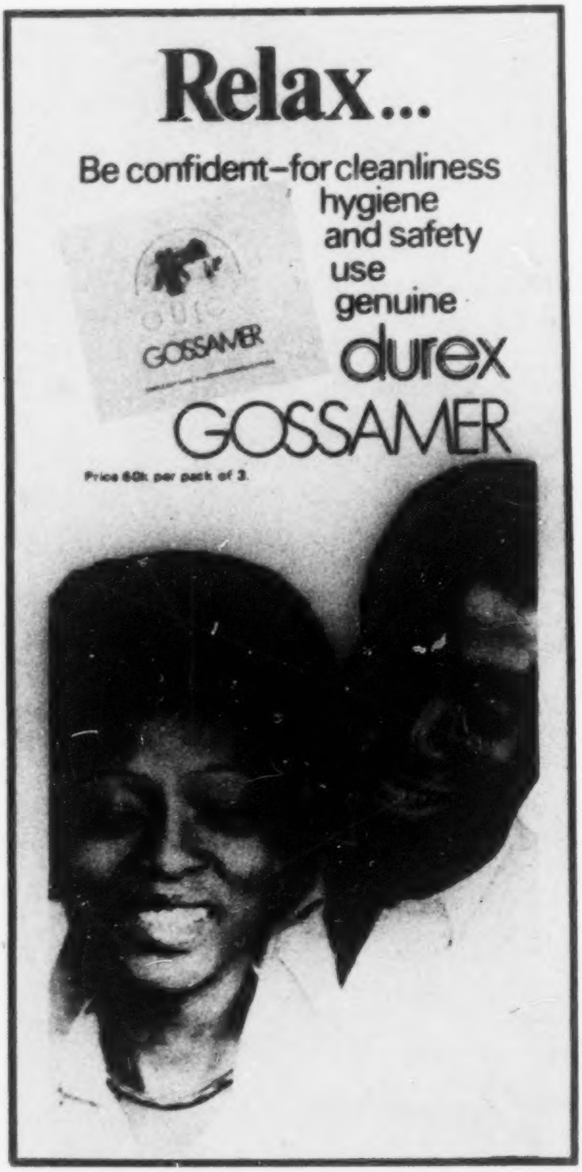
[a] Figures are for fiscal year.

[b] Estimated from expenditure figures at $4.00 (US) per gross.

Sources: 1975–78 data from Quinn (382).
1979–81 data from: US Agency for International Development (USAID) (70)
Family Planning International Assistance (FPIA) (175)
International Planned Parenthood Federation (IPPF) (77)
United Nations Fund for Population Activities (UNFPA) (51)
Pathfinder Fund (125)
UK Overseas Development Administration (UK ODA) (119)
Japanese Organization for International Cooperation in Family Planning (JOICFP) (485)

majority of teenagers begin having sexual relations about one year before they seek medical or clinical advice on contraception (29, 491, 492, 493). Some teenage girls experience side-effects with OCs and IUDs and have difficulty using diaphragms. Thus the condom, with its added prophylactic benefit, can be a good method for sexually active young people.

Programs to encourage adolescents to use condoms would be highly controversial in some countries, however (79, 139, 386, 402, 484). Some strategies that might increase usage without the need for a public campaign include: (1) providing young people with accurate information about the long-term dangers of STDs, including pelvic infection and the related risk of infertility for women (176), and (2) assuring that adolescents can buy condoms readily and anonymously from vending machines and self-service displays in shops and gathering places that they frequent (167).



**A growing proportion of condom buyers are women, and manufacturers have begun to direct some of their promotion toward women. This happy couple advertises condoms in a Nigerian women's magazine, *Africa Woman*.** (Courtesy of London Rubber Corporation)

### Offering an Appealing Product

In any culture, condoms will be more appealing if they are of good quality, free of visible defects, correctly sized, and as thin as possible (156, 479). Consumer preferences may vary somewhat in different areas, however. Consumer or market research can provide valuable guidance for any type of condom distribution program, finding out, for example,

- What types of condoms are most popular?
- What forms of packaging are most appealing and useful?
- How many condoms does a couple need each month?
- If condoms are being sold, what is a reasonable price?

Studies in the US (2), Sri Lanka (306), and Mexico (297) suggest that men prefer lubricated, receptacle-ended condoms. Colored condoms are popular in some countries. In Kenya red condoms are most popular, and in Japan black (373). USAID routinely provides Ansell *Tahiti* brand condoms, which are colored blue, green, pink, or yellow, to Nepal, Egypt, Thailand, and Jamaica. Little is known about preferences for variously shaped and textured condoms, although the extensive advertising campaigns in Japan and other developed countries emphasizing these qualities suggest that there is a large market for various condom types.

Condom packages should be attractive as well as convenient to store and handle. The inner strips in which condoms are enclosed should have adequate serrations between individual envelopes and be extremely easy to open (2, 28). In some areas private storage is a problem (409, 479). Thus boxes that contain condoms may need to be designed so that they do not stand out from other containers (270, 297). In the past, condoms donated to social marketing programs in Egypt and Nepal sometimes carried a different brand name on the inner strip than on the outer packaging (121, 417). The difference left users confused and suspicious of condom quality. In addition, it hampered the development of brand loyalty, which is important to the success of any marketing program (212). The donor, USAID, and the manufacturer, Ansell, now assure that inner packaging carries the same brand name as outer packaging or else no brand name.

Another factor that may influence packaging design is how many condoms couples use. A common assumption is about 100 per year (162), although 50–100 may be more realistic. For example, the Indian program estimates 72 per year (279) and the Bangladesh government estimates between 80 and 90 per year (194). In South Korea the standard procedure in family planning clinics was to hand out 12 condoms per month to users until a 1974 study found an average use rate of about 6 per month (270). In India alone, surveys in different areas have found average rates varying from 4.6 to 11–14 per month (37). Condoms are generally packaged 3, 6, or 12 to a box. No studies have evaluated which box size is preferred, although offering a variety of package sizes would appeal to the most consumers. For regular contraception, sizes larger than a 3-pack would be most convenient. The higher price of a 6- or 12-pack might reduce their appeal, however. In Jamaica it is hoped that a new 12-pack of *Panther* condoms will not only be convenient for users but also will allow self-service displays without pilferage—a problem with small items such as the 3-packs (19, 384).

Most programs that charge for condoms have found people willing to pay a fair price for them. This is partly because free or low-priced products are thought to be of poor quality (212, 428, 475). When the Korean Family Planning Association surveyed users in 1972 about the possibility of paying for condoms, only 6 percent said that they would stop using the method if payment were required (270). In a later South Korean survey users overwhelmingly approved of payment, arguing that it led to less wastage (368). In the Philippines a pilot marketing study found no difference in acceptance rates between condoms priced at three for $0.10 (US) and at three for $0.25 (487). These findings suggest that, as long as the price of condoms is comparable to the price of other commonly purchased items such as bread or cigarettes, charging a small amount may not reduce acceptability.

### Advertising and Promotion

Highly visible advertising and promotion compaigns nearly always increase condom sales. In Java and Bali, where *Karet KB* had been commercially available since 1974, initiation of an intense advertising campaign in 1975 boosted sales from 500 to 1,500 gross per month by 1976. When the ad campaign ended, sales dropped (1). In Bangladesh, when advertising was banned for three months in 1976 due to complaints that condom ads were too explicit, sales declined (35, 383). In India, a contest in Delhi, in which shopkeepers competed to produce the best promotional display for *Nirodh*, resulted in as many condoms being sold in one month as were usually sold in a year (17).

As advertising campaigns promote condom sales, they spread knowledge and awareness of condoms. This can be an important first step in some countries. For instance, 1976 Nepal World Fertility Survey (WFS) data showed that only 5 percent of ever-married women had heard of condoms. Even in Mexico, 1977 WFS data showed that only 42 percent of ever-married women had heard of condoms (462). In Bangladesh before the social marketing program started, 1975-76 World Fertility Survey data showed that only 21 percent of ever-married women had heard of condoms (462). After five years of *Raja* condom sales, in 1981 the percentage had risen to 59 percent (53). In Thailand an extremely visible promotion campaign led by Mechai Viravaidya, director of CBFPS, has greatly increased knowledge and acceptance of condoms since 1974 (76).

Advertising draws customers to a product and, in the case of condoms, may help to change its image. For instance, in Sri Lanka the condom marketing program tried to disassociate condoms from illicit sex by using slogans such as "For safe, sure planning of a family, use *Preethi*" (172). In Colombia the advertising slogan "Your child should not be an accident" tries to counteract the view of many men that using condoms is an affront to their masculinity (15). In Jamaica a theme of the *Panther/Perle* condom and OC marketing campaign is responsibility for one's actions. One slogan is "If you care about life" (12). (An earlier Jamaican slogan, "If you must . . . prepare with *Panther*" was withdrawn because customers and program officials thought it suggested illicit sex.) Various media are used to communicate these messages, including radio broadcasts, posters, point-of-purchase displays, and, occasionally, television advertisements.

Some family planning and social marketing programs have promoted condoms through special events such as distribution of free samples of condoms and slogan writing contests. In Egypt, *Tops* condoms have been handed out at festivals and sporting events to publicize their availability through the Family of the Future Program (5). In Thailand Mechai's efforts to desensitize family planning in general and condoms in particular are renowned (442). Condom "blowing up" contests for children, T-shirt sales, and a "cops and rubbers" program (which provided all policemen in Bangkok with condoms) are just some of the activities he has encouraged (76). In fact, in Thailand "Mechai" is used as a brand-name for condoms.

**Distributing free samples promotes a new product. Here, Egyptian volunteers package *Tops* condoms to hand out at a football match.** (IPPF/Jeremy Hamand)

Advertising and promotional activities have occasionally been barred by community objections or fear of these objections. In the US, it is estimated that open display of condoms in a drug store would increase sales by about 37 percent while eliciting complaints from only about 3 percent of customers (11, 283). Nevertheless, in the late 1970s between 40 and 50 percent of druggists in the US and Canada still did not display condoms either because they themselves disapproved or because they feared the disapproval of customers (166, 283). In San Jose, US, a subtle TV advertisement for condoms was suspended after one showing due to 100 immediate complaints. Although a letter-writing campaign was then mounted to encourage reinstatement of the ad, it was not shown again (22). The Regional Organization for Intergovernmental Cooperation and Coordination in Population/Family Planning in Southeast Asia (IGCC) recommends that, to alleviate community concern, advertisements should be very subtle at first and then gradually become more explicit if necessary (222).

In the Philippines the start of *Protec* condom sales and advertising in 1975 brought strong protest from the Catholic Women's League (CWL). The CWL contended that press advertisements and open displays of condoms would "degrade the morality of our people and result in the abuse of womanhood and deterioration of the sacred institution of marriage." The Population Center Foundation (PCF) countered that sales of condoms were based on the principles of free choice and individual conscience. During this so-called "condom war" the CWL boycotted and picketed shops that sold condoms. After about three months, PCF withdrew the condom advertisements, promised to promote periodic abstinence, and had condom packages labeled "Caution. Not to be dispensed to minors. For family planning use only." Ironically, the publicity generated by the "condom war" probably spurred condom sales (43, 389).

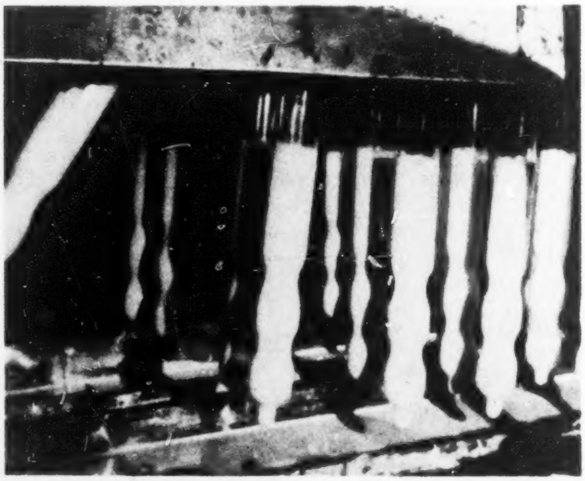
Although advertising can sometimes generate objections, providing a regular supply of high-quality condoms and promoting them vigorously are the keys to increasing use. Promotion can educate people about the effectiveness of condoms for contraception and for protection against disease, encourage people to try condoms, and then help to maintain regular use.

## MANUFACTURE

Making good-quality condoms requires well-trained technical staff and special production equipment. Most large condom plants are highly automated, and the factors that can affect quality—consistency of latex, humidity, temperature, and cleanliness—are carefully controlled. The major condom manufacturers each have slightly different procedures for compounding raw materials, for dipping forms in latex to produce thin condom membranes, and for the vulcanization, or curing, of finished condoms. These details are usually trade secrets.

The raw material of most condoms is latex, the sap of the rubber tree. Latex consists of a suspension of rubber particles in water. The rubber content of latex as it comes from the tree is usually about 30 to 36 percent and can vary according to region, season, and age of rubber trees. The latex is concentrated to greater than 61 percent and preservatives are added before shipping. On arrival at a production plant, the latex is analyzed. Before use, stabilizers, vulcanizing agents, coloring agents, and antioxidants to prevent premature aging are added. The exact combination of chemicals varies according to the source of raw latex and production procedures. The goal is a latex compound that forms a thin film of uniform strength, thickness, and consistency.

After compounding, the latex is poured into dipping tanks. Condom dipping is done automatically. A continuous conveyor system carries glass or metal condom-shaped molds slowly through a succession of processes. The molds pass in turn through a tank containing cooled latex, into drying ovens, through a second tank of latex, past a brush that rolls a ring on the open end of the condom, and then into ovens for drying and vulcanization. Finally, the condoms are stripped off the molds by water jets or brushes, the molds pass through a cleaning section, and the sequence starts over again. These machines are usually custom-designed by the condom manufacturer, and processes differ from one manufacturer to another. Molds may be dipped vertically or at a 45° angle; sometimes they are rotated in the latex, sometimes they are not. Japanese manufacturers do not vulcanize condoms on the dipping line, but instead cure them in bulk by extended tumbling at high temperature.



**Each glass mold leaves the tank of liquid latex coated with a thin membrane of rubber in the form of a condom. Most aspects of condom manufacture are highly automated.** (Sagami Rubber Industries)

The extent of vulcanization is important to the quality of condoms. Rubber that is undervulcanized is softer, more flexible, and more difficult to handle than rubber that is thoroughly vulcanized. The more vulcanized the rubber is, the tougher but less flexible it is. Vulcanization continues as packaged condoms age until a plateau of toughness and reduced flexibility is reached. If condoms are stored for many years, strength and toughness will eventually decline (381).

How the condoms are handled after they come off the molds also varies. Indeed, a British technology used in India produces a completely cured, powdered, and rolled condom off the dipping line, requiring no further finishing. In the usual case of wet-stripped condoms, they are tumbled in bulk to complete drying and/or to remove excess powder, which may have been added before removal from the molds. The condoms then are electronically screened for pinholes, and samples are tested before packaging. Lubrication may be carried out automatically as each condom is wrapped or, in the Japanese process, by tumbling the bulk condoms with lubricant before wrapping.

### Manufacturing Condoms in Developing Countries

Worldwide, the estimated production capacity for condoms is about 34 million gross per year, or about 5,000 million pieces (276, 480)—more than enough to supply each of the world's estimated 40 million users with 100 condoms a year. Actual annual production is not known. (See Table 5.)

Most condoms are produced by companies based in developed countries. Japan produces more condoms than any other country, in part because of the huge domestic market. Three Japanese companies, Fuji Latex, Okamoto Riken Gomu, and Sagami Rubber Industries, each have the capacity to produce 500 million or more condoms per year. Sagami Rubber is a major international supplier. So are Ansell Incorporated in the US and London Rubber Corporation (LRC) International, which has plants in several countries (154, 276, 480).

About one-third of production capacity is in developing countries. The People's Republic of China has the largest capacity of any developing country—about 700 million per year (276). India and South Korea each can produce between 300 and 400 million condoms per year (480). Most plants in developing countries produce between 50 and 100 million condoms per year, largely for domestic markets. Plants of this size have been established in such countries as Malaysia and Brazil.

Producing high-quality condoms at a profit in a developing country is difficult, particularly in the early years of operation. First, it may be hard to obtain and pay for machinery. The Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) estimates that it costs between $5 and $8 million (US) to set up a plant that can produce over 70 million condoms per year—the minimum necessary to use currently available equipment efficiently (159). Second, the skills of dipping, heating, and cooling latex to produce a uniform film must be mastered. Other technical problems that may be encountered are:

**Table 5. Estimated Annual Condom Production Capacity, by Country**

| Country | Capacity (in Gross[a]) |
|---|---|
| DEVELOPING COUNTRIES | |
| **Argentina** | 500,000 |
| **Brazil** | 700,000 |
| **China, People's Republic of** | 5,000,000 |
| **India** | 2,500,000 |
| **Korea, Rep. of** | 2,400,000 |
| **Malaysia** | 1,000,000 |
| **Mexico** | 60,000 |
| **Subtotal** | 12,160,000[b] |
| DEVELOPED COUNTRIES | |
| **Australia** | 100,000 |
| **Czechoslovakia** | 500,000 |
| **German Democratic Rep.** | 400,000 |
| **German Federal Rep.** | 600,000 |
| **Italy** | 400,000 |
| **Japan** | 8,000,000 |
| **South Africa** | 270,000 |
| **Spain** | 250,000 |
| **United Kingdom** | 4,000,000 |
| **United States** | 7,350,000 |
| **USSR** | 400,000 |
| **Subtotal** | 22,270,000 |
| **TOTAL** | 34,430,000<br>(or 4,960 million condoms) |

[a] One gross = 144 condoms

[b] Singapore is reported to be establishing a large-capacity manufacturing plant (480).

Sources: Free (154), Koyama (276), Windsor (480)

- acquiring high-grade latex,
- producing a consistent latex compound,
- maintaining a constant temperature and humidity level in the plant,
- running a plant efficiently day and night when power supplies vary,
- acquiring and installing spare parts for production machinery (154).

A few large companies have sold equipment and expertise to developing countries interested in condom production. For instance, the People's Republic of China, with support from the United Nations Fund for Population Activities (UNFPA), recently bought equipment and technical information from Akwell Industries (now Ansell) to produce lubricated and better packaged condoms. Other companies have made other arrangements for production in developing countries. For example, Sagami operates a subsidiary in Malaysia (276), and LRC operates a joint venture with local participants in India (480).

Some observers have suggested that the most efficient way to meet worldwide demand now is through a few, very large, highly automated plants, as is currently done (374). Forty million current users requiring an average of 100 condoms each per year would need 4,000 million condoms a year. Thus estimated worldwide capacity of about 5,000 million appears sufficient to meet current needs. Furthermore, the highly automated processes used in Japanese, American, and British plants cannot always be adapted to other environments. Where local demand is expected to increase and where governments supply condoms to national family planning programs, local production might be considered, however. One economically feasible option for many countries may be to import condoms in bulk or in plain foil or plastic strips and then provide the outer and possibly also the inner package (153). Unpackaged condoms in large quantities are relatively inexpensive, since packaging may account for at least half of the final wholesale price. Packaging operations are labor-intensive and so provide jobs with relatively little capital investment. Also, although imported products often are considered more desirable, local packaging operations can more easily use local languages and appeal more specifically to local tastes. Local packaging of imported or donated condoms takes place in Bangladesh, Thailand, and El Salvador.

## QUALITY CONTROL

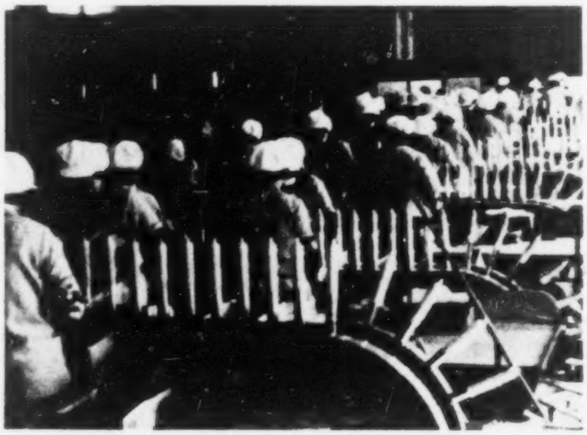
All major condom-producing countries (except South Korea) and a number of importing countries have national standards for condom quality (151, 264). The standards specify physical characteristics and prescribe the type of tests used to measure these characteristics. Standards generally require:

- visual inspection for packaging defects,
- measurement of length, width, thickness, and/or mass,
- a test for holes,
- a test of strength.

The specific tests required, the number of condoms to be tested, and the percentage that must pass the tests vary from country to country (see Table 6). While standards differ somewhat, condoms made by the major manufacturers are of high quality and meet all national standards. Defects that could cause failure are extremely rare.

Most national standards require that individual condoms be sealed in airtight envelopes and then packaged in paper containers. Most specify that package labels show the manufacturer's name and an expiration date—usually ranging from no more than three to five years after manufacture. The US and Japanese standards simply require that the date of manufacture be printed on packages (38, 246).

Specifications for condom length, width, thickness, and mass vary from country to country, and not all countries list specifications for all these characteristics. Most national standards specify a minimum length of 160 mm. For width, most standards specify a permissible range, usually about 45 to 55 mm. Specifi-



**Every condom is electronically tested for pinholes before it leaves the factory. Before the test, workers roll the condoms onto electrodes.** (Sagami Rubber Industries)

## Table 6. Summary of National Condom Standards of Selected Countries

| Country, Date of Implementation & Ref. No. | Authorizing Institution | Dimensions | Test for Holes[a] | Test for Strength | Other Tests and Specifications |
|---|---|---|---|---|---|
| **Australia 1980** (433) | Standards Association of Australia | L ≥ 160 mm.<br>W = 47-56 mm.<br>T ≤ .08 mm. | Water leakage test. | Air burst test—bursting volume ≥15 liters. | Colorfastness test.<br>Packaging and labeling specifications including instructions and 5-year expiration date.<br>Storage specifications. |
| **Canada 1978** (201) | Health and Welfare Canada | L ≥ 160 mm.<br>W = 45-55 mm between rim and 80 mm from closed end, and ≤ 70 mm within 80 mm from closed end. | Water leakage test for new condoms and condoms aged in air oven 12 hours at 68-72°C. | Air burst test—bursting volume ≥ 25 liters, bursting pressure ≥ 1 kPa, for new and aged condoms. | Packaging and labeling specifications including 5-year expiration date. |
| **India 1980** (220) | Ministry of Health and Family Welfare | L ≥ 160 mm.<br>W = 45-55 mm.<br>T ≤ .07 mm.<br>M ≤ 1.6 g. | Water leakage test for condoms failing air inflation test. | Tensile test—New condoms: average strength ≥ 17 MPa; average elongation ≥ 650%. Condoms aged in air oven for 96 hours at 69-71°C: average strength can be 30% lower; average elongation, 15% lower. | Condoms inflated to 150 mm diameter and examined for defects.<br>Colorfastness test.<br>Packaging and labeling specifications including 3-year expiration date.<br>Storage specifications. |
| **Israel 1976** (434) | Standards Institution of Israel | L ≥ 160 mm.<br>T ≤ .16 mm.<br>M ≤ 1.7 g. | Water leakage test. | Tensile test—New condoms: strength ≥20 MPa; elongation ≥650%. Condoms aged in air oven for 168 hours at 70°C: strength and elongation can be 25% lower. | Condoms inflated with air to 163-167 mm diameter and examined for defects.<br>pH test. pH must be 6-8.<br>Packaging and labeling specifications including 3½-year expiration date. |
| **Japan 1966** (246) | Japanese Standards Association | L ≥ 170 mm. | Electrical test for pinholes. Required resistance >200 kiloohms. | Tensile test—New condoms: strength ≥ 20 MPa; elongation ≥600%. Condoms aged in air oven at 70°C for 72 hours: strength ≥20 MPa; elongation ≥540%. | Packaging specifications. |

Note: The following countries also have national standards for condoms: Denmark, Finland, Hungary, Netherlands, Norway, China (draft), Singapore (draft), and South Africa.

L = Length, excluding any reservoir unless otherwise stated
W = Width, usually within 70-90 mm of rim (one-half circumference)
T = Thickness (single wall)
M = Mass

cations for the maximum thickness of the condom membrane range from .07 to .16 mm. The maximum mass permitted is between 1.5 and 1.9 g, depending on the size and surface type of the condom.

Condoms are tested for holes in two different ways: (1) nearly all manufacturers electronically screen all condoms for pinholes, and (2) national standards require sample condoms to be tested for holes. Electronic screening works because rubber does not conduct electricity, so electric current cannot pass through an unflawed condom. Condoms are rolled by hand onto tube-shaped electrodes and then either passed through an electrolyte solution (wet system) or across a fine mesh screen (dry system). If current passes through a condom, the condom is rejected. Condoms that pass the test are rerolled and sealed in foil or plastic strips. Most national standards require testing for holes by filling sample condoms with 300 ml of water and then rolling them on absorbent paper to check for leakage. In addition to the water leakage test, the Indian, Israeli, and Malaysian standards specify inflating sample condoms with air to a diameter of between 125 and 167 mm and then checking for defects and holes. The Japanese standards require an electrical test for pinholes in addition to that carried out by manufacturers.

A major difference among national standards involves one aspect of testing condom strength. Most manufacturing countries, including the US, Japan, Britain, and India, and one importing country, Israel, use the tensile test. In this test small sections are cut from the middle of a condom and mechanically stretched until they break. The load each section withstands before breaking and the length of the section when it breaks are measured. Standards are expressed in terms of tensile strength measured in megapascals (MPa) (one MPa is equal to a force of about 10 kilograms per square centimeter of latex surface) and elongation at break (in which the length of the section when it breaks is expressed as a percentage of the unstretched length) (260). New Ansell *Raja* brand condoms (49 mm width) have a tensile strength of between 25 and 35 MPa and an elongation at break of about 800 percent (157).

**Table 6 (Continued)**

| Country, Date of Implementation & Ref. No. | Authorizing Institution | Dimensions | Test for Holes[a] | Test for Strength | Other Tests and Specifications |
|---|---|---|---|---|---|
| **Malaysia 1973** (435) | Standards Institution of Malaysia | L ≥ 160 mm; for reservoir-ended, ≥ 175 mm.<br>W = 44–56 mm; for contoured condom, 44–70 mm.<br>M ≤ 240 g/gross. | Water leakage test. | Water volume test—New condoms: must hold 3 liters without breaking. Condoms aged in 70°C air oven for 168 hours: must hold 2 liters. | Condoms inflated with air to diameter of 125 mm and examined for defects.<br>Packaging and labeling specifications including expiration date and words "for one-time use only."<br>Storage specifications. |
| **Sweden 1973** (440) | Social Welfare Board | L ≥ 170 mm.<br>W = 49–56 mm.<br>M ≤ 17 g/10 condoms. | Water leakage test. | Air burst test—average bursting volume ≥ 25 liters average (standard deviation < 25%). | Packaging and labeling specifications. |
| **United Kingdom 1973** (72) | British Standards Institution | L ≥ 160 mm.<br>W = 49–56 mm; for contoured condom, ≤ 70 mm.<br>T ≤ .08 mm.<br>M ≤ 1.7 g for smooth surface; 1.9 g for textured surface. | Water leakage test. | Tensile test—New condoms: average strength ≥ 20 MPa; average elongation ≥650%. Condoms aged at 69–71°C for 12 hours: average strength ≥ 17 MPa, average elongation ≥600%. | Colorfastness test.<br>Packaging and labeling specifications including instructions and 5-year expiration date.<br>Storage specifications. |
| **United States 1977** (38, 437) | American Society for Testing and Materials | L = 170–190 mm or 150–170 mm.[b]<br>W = 49–55 mm or 47–51 mm.[b]<br>T = .03–.09 mm.<br>M = 1.50–1.95 g.[b] | Water leakage test. | Tensile test—New condoms: mean strength ≥24 MPa, mean elongation ≥750%; specimen[c] strength ≥17 MPa, specimen elongation 675%. Aged 12 months or more or accelerated at 68°–72°C for 164–168 hours: mean strength ≥19 MPa, mean elongation ≥700%; specimen strength ≥17 MPa, specimen elongation 625%. | Packaging specifications.<br>Storage specifications. |

[a] In water leakage test, condom is filled with 300 ml of water and rolled over absorbent paper, which is then examined for wetness. Not rolled on paper in India.

[b] Depending on intended condom size

[c] No more than one condom sampled can have tensile properties below specifications for specimen strength and elongation.

By contrast, other countries, including Canada, the Scandinavian countries, and Australia, use the air burst test. This test involves inflating a condom with air at a rate of 25 to 30 cubic decimeters per minute until it bursts. Standards are established for bursting pressure (in kilopascals, or kPa—one thousandth of a MPa) and bursting volume (in liters). New *Raja* condoms have a bursting pressure of about 1.5 kPa and a bursting volume of 20–25 liters (157).

Malaysia evaluates strength through a water volume test. Condoms are slowly filled with water while the base of the condom is supported from below. New condoms are required to hold three liters of water; aged condoms, two liters (435). Whether this test, which is cheap and easy to administer, is an adequate test of condom strength and how it compares in results with the tensile and air burst tests are not known.

The tensile test and the air burst test each have their advocates. The tensile test is an established method of testing the quality of latex rubber (235, 340). Manufacturers use the test during condom production to monitor and guide the production process (304, 437). As a result, they have considerable experience with this test. According to proponents, tensile test results are less affected by slight changes in the size or thickness of a condom than air burst test results (340, 437). On the other hand, advocates of the air burst test prefer it because it tests the entire condom rather than a small portion of the membrane (266, 340). Studies comparing the tests are few (157, 496), and establishing equivalence will be difficult since results of both tests vary for different condom brands and among testing facilities (74, 496). Results of one study suggest that, as condoms are artificially aged to varying degrees, results of the two tests change in a similar manner (157).

While there are differences of opinion about these tests, it is clear that current national standards are adequate to assure that condoms are of good quality. The high effectiveness rates seen in some clinical trials testify to that. It is not certain, however, how low test readings could be and still prevent breakage during actual use of an appreciable proportion of condoms. In the

# ISO STANDARD FOR CONDOMS

There are eleven parts to the International Organization for Standardization (ISO) standard for condoms. Seven parts—the specifications for length, width, colorfastness, tensile properties, bursting properties, packaging and labeling, and storage—have been approved by the ISO Technical Committee on Mechanical Contraceptives and published in final form. Four parts—the tests for holes, mass, resistance to storage and the sampling plans and requirements—were approved at a September 1982 meeting of active members of the technical committee and are awaiting approval by the full committee. The complete, approved standard may be published in 1983.

Under the ISO international standard, condom quality is evaluated by examining samples from inspection lots. Each lot must consist of condoms of the same shape, length, width, and surface type. A lot should consist of no more than 150,000 condoms and usually consists of at least 35,000. The maximum percentage of condoms in a lot that is allowed to depart from ISO specifications is called the Acceptable Quality Level (AQL).

The number of condoms sampled and the number of sampled condoms that are permitted to fail a test without requiring rejection of the entire lot are determined by reference to published tables. The object of the ISO standard is to assure that a lot containing more than the percentage of defective condoms specified by each AQL has less than a 5 percent chance of acceptance. The table below shows the proposed AQLs, sample sizes, and maximum number of failures permitted (223, 267).

| Standard | AQL | Sample Size | Maximum Permitted Failures |
|---|---|---|---|
| **Length, width, mass** | 4.0 | 13 | 1 |
| **Holes** | 0.4 | 200 | 2 |
| **Colorfastness** | 4.0 | 13 | 1 |
| **Strength** | | | |
| **Tensile test** | 2.5 | 13 | 1 |
| **Air burst test** | 1.5 | 80 | 3 |
| **Packaging & labeling** | 1.0 | 13 | 0 |

Note: Assumes single sampling plan and normal inspection conditions. Manufacturers with very good or very poor quality records often sample fewer or more condoms per lot, respectively.

### Length, Width, and Mass

Length, width, and mass are tested jointly. A class I condom must have a minimum length of 160 mm and be 52 ± 2 mm wide (as measured up to 85 mm from the open end). A class II condom must have a minimum length of 150 mm and be 48 ± 2 mm wide (224, 225, 267). Class I condoms must have a mass not greater than 1.7 grams if smooth-surfaced or 2.0 grams if textured. Class II condoms must have a mass not greater than 1.5 grams if smooth-surfaced and 1.8 grams if textured (231, 267).

### Holes

In the test for holes, a condom is freely suspended from a mount, filled with 300 cc of water at room temperature and then checked for leakage (227, 267).

### Colorfastness

The approved test for colorfastness involves a simple visual inspection. White absorbent paper is wrapped around a wet condom and checked for staining after 16 to 24 hours (226).

### Strength

The Technical Committee was unable to agree whether to call for the tensile test or the air burst test. Currently, the standard would allow either or both tests "as agreed between the parties concerned, which may include two or more of the following: purchaser, standardizing body, regulating authority and supplier" (223, 267).

The tensile test uses a 20 mm wide ring cut 80 mm from the open end of a condom. Condoms tested less than 12 months after manufacture must have a tensile strength of at least 17 megapascals (MPa) and an elongation at break of at least 650 percent of unstretched width. Older condoms must have a tensile strength of at least 15 MPa and an elongation at break of at least 600 percent (232, 267).

Requirements for the air burst test differ according to the size as well as the age of the condom. For condoms tested less than 12 months after manufacture, bursting volume must be at least 15 liters for class I condoms and 13 liters for class II condoms. The minimum acceptable bursting pressure must be one kilopascal (kPa). For older condoms bursting volume must be at least 12 liters for class I condoms and 11 liters for class II condoms. Minimum bursting pressure must be 0.9 kPa (229, 267).

### Resistance to Storage (Aging)

The proposed test involves artificially aging unopened packages of condoms in an oven at 70° ± 2°C for 166 ± 2 hours and then keeping them at 23° ± 5°C for 12 to 96 hours. The condoms would then be unwrapped, examined for signs of deterioration, and tested for strength using the values proposed for condoms 12 months old or older (see above) (230).

### Packaging and Labeling

Under the approved specifications, each condom must be individually sealed under hygienic conditions. Condoms must then be packaged so that they are adequately protected during transport and storage. Packaging materials should not mildew or attract insects. Each package must be marked with manufacturer's name, trademark, and an identification reference, such as a batch number. Instructions for use must be included in the package. An expiration date is not mandatory (233).

### Storage

The recommendations for storage state that condoms should not be stored longer than necessary, especially in warm climates. They should be kept in a cool, dry place in protective containers and should not come in contact with petroleum-based substances such as petroleum jelly. As soon as any condom shows signs of deterioration such as brittleness or stickiness, it should be discarded (234).

only study published to date, involving five users and 30 newly purchased and 150 artificially aged condoms, there were no breakages in actual use for condoms from a group with air burst volumes of about 18 to 24 liters, but about 30 percent broke when air burst volumes were 6 liters or less (160).

### International Standards

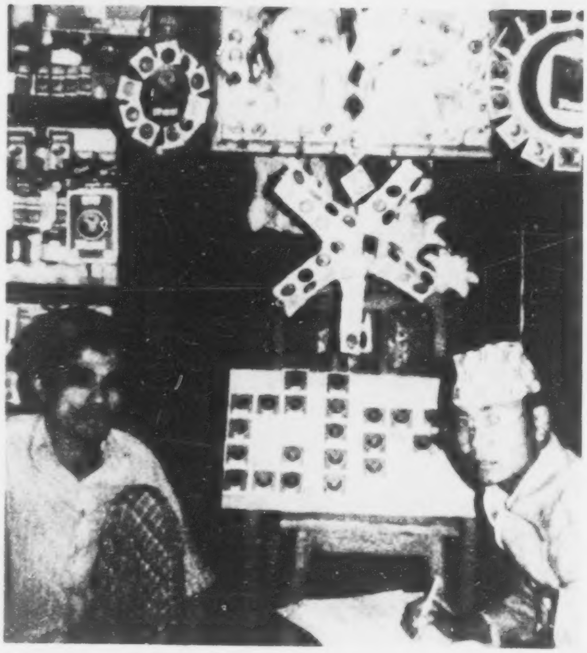
The current system of national standards has two major limitations. First, variations among national standards make the production and international distribution of condoms unnecessarily difficult and expensive (471). Arne Vogel, Secretary of the International Organization for Standardization (ISO) Technical Committee on Mechanical Contraceptives, cites the following example:

> . . . when SIDA [the Swedish International Development Authority] bought condoms from Japan for the Family Planning Programme in India, the purchase was based on the Swedish regulations and the goods were tested by a Swedish Governmental Test Institute. In Japan the condoms were tested by a Japanese Export Authority according to Japanese regulations as they must be approved under these regulations before they could be exported. Finally when the condoms arrived in India they had to be tested by an Indian laboratory according to Indian regulations before they could leave the port and be distributed to the consumers in the country. (471)

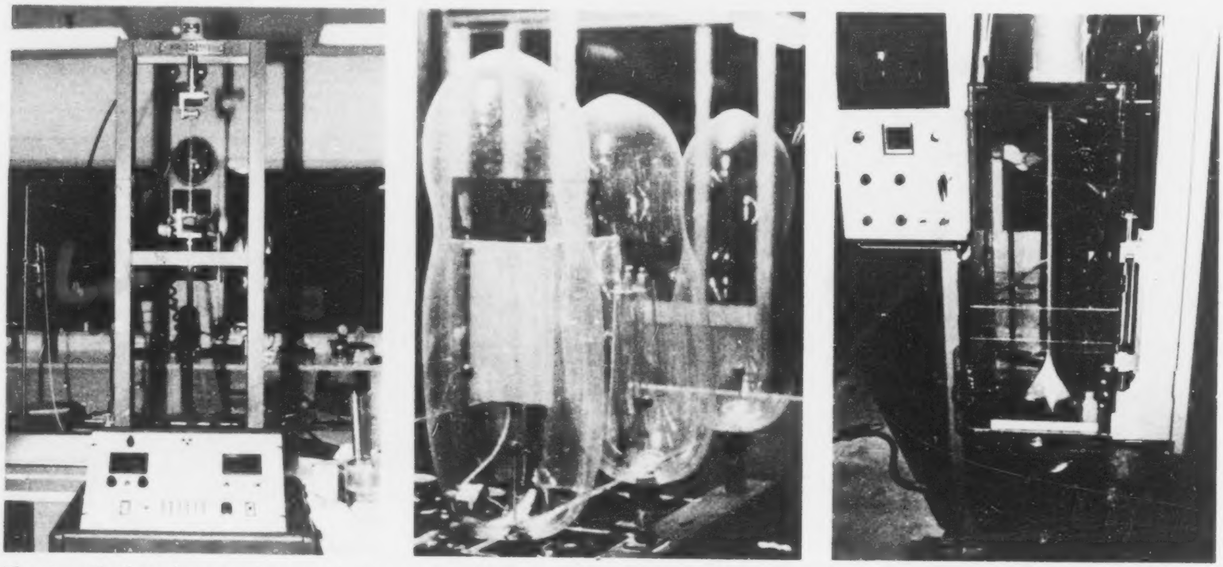
Second, many countries, particularly developing countries, do not have national condom standards or the capability to test whether standards are being met (303).

To try to resolve these problems, the ISO Technical Committee on Mechanical Contraceptives has been working since 1974 to establish an international standard for latex rubber condoms (see box, facing page). Currently 14 countries are active members of the committee, including several producing countries and some importing countries. Many of their representatives are employees of donor agencies, manufacturers, or standards institutions. Some 22 other countries are observers; that is, they are kept informed of the progress of the technical committee's work.

The impact of the international standard will largely depend on the willingness of producing and importing countries to adopt and enforce it. While some major producers—including Japan, China, India, and South Korea—are not active participants on the ISO committee, a number of factors should encourage widespread compliance. First, the current national standards of several producing countries, including the US and UK, already equal or exceed the international standard. Manufacturers in these countries will not need to change procedures. Second, the largest international condom manufacturers have the flexibility and resources to meet a variety of standards. Third, the General Agreement on Tariffs and Trade (GATT) requires signatories (which include the US, UK, and Japan) to comply with international standards or else justify their noncompliance (469).



**Nepalese shopkeepers promote *Dhaal* condoms with an imaginative point-of-purchase display.** (Westinghouse Health Systems)



**The strength of condoms can be tested in several ways. Some manufacturing countries require a tensile test, in which cross-sections of condom are stretched until they break (left). Some importing countries require an air burst test, in which condoms are inflated to the breaking point (center). Yet another possibility is the water volume test, in which a condom must hold a measured amount of water without breaking (right).** (Left—Ansell Inc.; center and right—Sagami Rubber Industries)

## Condom Testing and Program Planning

All rubber products, including condoms, eventually deteriorate. Good-quality condoms that are stored correctly in a temperate climate remain in good condition for at least five years (150, 265). If condoms are stored under extremes of temperature and humidity or exposed to insects or mold, quality may deteriorate faster.

The best way to keep deteriorated condoms from reaching users is to develop a logistics system that avoids storing any condoms for long periods. If the flow of supplies can be closely matched to demand, storage time can be minimized. In Bangladesh, sales of *Raja* condoms are so brisk that none are stored long enough to risk deterioration (346). At the same time, however, the quality of condoms stored for free distribution by government programs has been questioned (346).

In instances where condoms have been stored for some time and doubts arise about their quality, batches would have to be checked to avoid either throwing out the batch unnecessarily or distributing unreliable condoms. Severely deteriorated condoms are obvious; they are yellowed, stuck together, and will not unroll. At earlier stages of deterioration, however, testing with instruments would be necessary. Testing could be done when a batch of condoms approached an expiration date established on the basis of experience. Alternatively, they could be tested periodically throughout the duration of storage. PIACT, which sells field testing equipment for condoms, advocates this approach, arguing that different batches of condoms may deteriorate at different rates (150, 157). Furthermore, PIACT studies show that a small proportion of condoms in a batch start to deteriorate before the others. According to PIACT, finding these few deteriorating condoms could tell program managers that the batch should be distributed for immediate use before more extensive and more severe deterioration takes place (150, 157).

A further question is which test to use. PIACT and others advocate the air burst test on the grounds that weak spots, which can develop anywhere on the condom surface, might be missed by the tensile test (74, 157, 266, 340). Others would prefer the tensile test because comparisons could be made with manufacturer's records of tensile test results for specific types or even batches of new condoms (341, 353). Still others have suggested that a water volume test—such as one in which condoms are filled with one liter of water and suspended from the open end for one minute—could be a good, simple test to evaluate condoms in the field (437).

**About one-quarter of the world's condom users are Japanese, and manufacturers offer them a variety of shapes, colors, and brands. Some, like this 12-pack, are elaborately packaged.** (Fuji Latex Co.)

Although currently there is disagreement about the best way to test condom quality, experts agree that modern condoms are high-quality products with great potential for family planning and for protection againt disease. Much of that potential is not being used—in part due to myths and misperceptions. Experience over the last decade shows that lively advertising and other promotion can overcome doubts and ignorance about condoms. New and more extensive distribution schemes are bringing condoms to new users. As promotion and distribution continue to expand in the coming decade, condoms can play a more important role as an effective, safe, and acceptable method of family planning.

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